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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

WILLIAM BARNES, et al., Plaintiffs	:	CIVIL ACTION
vs.	:	
THE AMERICAN TOBACCO COMPANY, et al.,	:	
Defendants	:	NO. 96-5903-CN

- - -

Wednesday, September 17, 1997
Philadelphia, Pennsylvania

- - -

Videotape deposition of A. JAMES GIANNINI, M.D., taken pursuant to notice at the law offices of CONRAD O'BRIEN GELMAN & ROHN, P.C., 1515 Market Street, 16th Floor, Philadelphia, Pennsylvania, at 10:33 o'clock a.m. on the above date, before Dianna R. Pugliese, Registered Merit Reporter, Certified Shorthand Reporter-NJ, Notary Public.

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(Continued . . .)

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A. JAMES GIANNINI, M.D.

MR. FOWLER: My name is Greg Fowler. I'm here representing Lorillard and Brown & Williamson. This deposition had been scheduled to start at 9:00 in the morning by arrangement with Mr. Sheller's office, between Mr. Sheller's office and myself. Because Dr. Giannini needs to catch a flight today he needs to leave here today at 3:00. I had apprised Mr. Sheller's office of that and through missteps, no way the responsibility of Mr. Becnel, we're not getting started until 10:30. And I should add, the deposition starting at 10:30 was by no fault of Dr. Giannini's or of anybody on the defense side. It was a scheduling problem unconnected with anybody in this room.

But anyway, to make a long story short, we're starting here after 10:30 and Dr. Giannini needs to leave at 3:00 and that was previously made known to plaintiff's counsel. And there's no problem with us stopping at 3:00 from your point of view, Mr. Becnel?

MR. BECNEL: No, I understand if you made that agreement with people here in Pennsylvania, I can't do anything about it and I won't cause any problem.

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A. JAMES GIANNINI, M.D.

MR. FOWLER: Thank you very much.

MR. KLEIN: Just so we're clear, we've been doing these depositions that an objection by one is an objection by all; okay?

MR. BECNEL: That's fine.

VIDEOGRAPHER: We're now on the record. Today is Wednesday, September 17th, 1997. Would you please swear in the witness.

- - -

A. JAMES GIANNINI, M.D., having been duly sworn, was examined and testified as follows...

BY MR. BECNEL:

Q. Dr. Giannini, you have the right to read and sign this deposition. Do you choose to do that, sir?

A. I choose to do so, yes.

Q. And if I ask you a question that you don't understand, please stop me. Otherwise, we'll assume you understood the question and the answer will be appropriate.

A. Very good.

Q. Okay. Dr. Giannini, when were you first retained in the litigation here in Pennsylvania?

A. I believe -- I can't give you an exact date

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but I believe sometime in the summer or late spring.
Q. Of?
A. This year.
Q. Did you receive a letter retaining you as an expert in this case?
A. I don't believe so.
Q. How were you notified that you were retained?
A. By telephone.
Q. And who retained you, sir?
A. It would be one of the legal counsel at Shook, Hardy & Bacon.
Q. And what was your assignment?
A. To see if I'd be interested in being involved in this case.
Q. All right. And did you express an interest to be involved in this case?
A. After I read some preliminary material.
Q. All right. What preliminary material was provided to you to make you decide to be involved in this case?

MR. FOWLER: Object to the form of the question.

A. I believe it was some transcripts.
Q. Transcripts of what?

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A. The -- some of the plaintiffs.
Q. Some of the plaintiffs in the Pennsylvania litigation?
A. Yes, sir.
Q. Nothing else?
A. To the best of my memory, that is correct.
Q. All right. After you read the transcripts of the plaintiffs, what did you think was important about what was said in those depositions that you thought you could be of help to this litigation?
MR. FOWLER: Object to the form.
A. I thought that the material as presented at that time impinged on the area of addiction, which is a particular area of interest of mine.
Q. You, after receiving that, were you given any additional information in order to formulate an opinion?
A. Yes, sir.
Q. All right. Tell me all of the information in terms of listing the time you got it and what you were given, since we're trying to abbreviate this deposition and move as quick as possible?
A. Okay. To the best of my recollection, I was given transcripts of plaintiffs, transcripts of some

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of the family members, and I was given those over a period of time late spring, early summer, until August, through August. And I was also given at some time in August a report prepared by a Dr. Michals, a report prepared by a Dr. Savard, and a report prepared by Dr. Benowitz, a report prepared by Dr. Henningfield, and one other gentleman, his name escapes me but he's at the Institute of Living.

Q. All right. Did you receive any original medical records on any of the plaintiffs?

A. No.

Q. You've never reviewed any of the summaries of their medical records from anyone?

MR. FOWLER: Object to the form.

A. I reviewed the summaries prepared by Dr. Savard.

Q. Other than Dr. Savard?

A. Not to my best memory.

Q. Did you receive any edited transcripts of any of the deposition testimony?

A. I'm not sure what an edited transcript is.

Q. Meaning not -- let's say if a transcript is 300 pages, they reduced it to 20 pages so that you just get what's considered highlights of the

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deposition rather than the whole transcript?

A. To the best of my knowledge -- remembrance, all the transcripts were full transcripts.

Q. All right. And you read those?

A. Yes, sir.

Q. Did you keep a time record of when you did certain things in connection with this case?

A. Yes, sir.

Q. And how do you keep time records?

A. When I start reading, I'll write it on a piece of paper. When I finish reading, I'll note that time.

Q. And do you also maintain those records, those time records, for billing purposes?

A. For a 30 -- during that billing period, that 30-day billing period, yes.

Q. All right. And then what do you do with the records?

A. Well, I give them to a secretary in my office, she sends the bill to the attorney's office, and we wait to see if there's a question another 30 days and then we dispose of it.

Q. So the only billing records you maintain, then, are your electronic billing records or not

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original handwritten notes but the notes that you sent off to the counsel that's retained you or the person who's going to pay your bill?

A. For one year.

Q. All right. You only keep it for one year?

A. That is correct.

Q. So you do not follow the IRS regulations of keeping bills for the tax period of three years, sir?

MR. FOWLER: Object to the form.

A. My accountant knows the IRS rules. I don't.

Q. Well, do you keep them for one year or three years, sir?

A. To the best of my knowledge, I keep them one year.

Q. And then you dispose of them?

A. That is correct.

Q. And if that's in violation of IRS regulations on billing in how long you keep financial records, then you do not know what the IRS regulations are, do you?

A. I cannot comment on IRS rules.

Q. Do you feel that you're obligated, sir, ethically, to follow those rules?

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MR. FOWLER: Object to the form of the question.

A. As I said, I don't know what the IRS rules are and I would have to consult with my accountant before I could respond.

Q. Are you a U.S. citizen, sir?

A. Yes, I am.

Q. And you know that IRS regulations are promulgated for people in the United States who are U.S. citizens and others to follow?

A. Yes, sir.

MR. FOWLER: Object to the form.

Q. All right. Have you, sir, written any reports in connection with this case?

A. No, sir.

Q. You've not written any reports to anyone?

A. I've written my opinion on this case.

Q. That's a report. Is that the only report that you've written?

MR. FOWLER: Well, I'm going to object. You can't tell him what a report is or what a written opinion is. Ask him questions. Don't correct him or don't purport to correct him.

Q. Did you write a report in this case, sir?

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A. A report, no.
Q. What did you write in this case?
A. I wrote an opinion.
Q. And was your opinion a three-page opinion?
A. I don't remember the number of pages.
Q. All right. I'm going to show you Exhibit 1 and ask if that is what you wrote in connection with this case?
A. Yes, sir, it is.
Q. All right. Were you requested to write this report, sir?
A. I believe so.
Q. Do you know why you were requested to write this report?
A. It is my understanding that's standard practice in a case.
Q. Did you consider this a report in compliance with the federal rules and pretrial requirements of this Federal Court in this case?

MR. FOWLER: Object to the form of the question. Calls for a legal conclusion.

A. My knowledge as a medical doctor, not as an attorney, is in this sort of case, it is standard for me to write an opinion.

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Q. Other than the opinion expressed in this three-page opinion or report, can you tell me if you have any other opinions or supplemental reports or opinions not found in this document?

MR. FOWLER: Object to the form. Are you asking him for additional written materials?

Q. Any further materials, written or otherwise, that is not outlined in this three-page report or opinion.

A. This constitutes my sole written opinion.

Q. All right. So the four corners of these documents would be your sole opinion in this case?

A. My sole written opinion.

Q. All right. We'd like to mark the following and introduce into evidence as Exhibit 1 a copy of his report. That is your signature on this opinion or report?

A. Yes, sir.

Q. Did you write this or did someone assist you in writing this report, sir?

A. I wrote it.

Q. And the information contained in that report is true and correct to the best of your ability; is that correct?

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A. To the best of my ability, it is true.

Q. The information that you obtained in this report was gleaned from what documents to determine, for example, how many people smoke in the United States and things of that type?

MR. FOWLER: Object to the form. It's overly broad. You can answer it in general terms if you can answer that question.

A. It's based on a lifetime of practice, my training and education.

Q. All right. And I notice that you use some information from 1993, even though you were retained in 1997 and wrote your report in 1997. Is there any reason why you used information based in 1993 rather than current, up-to-date information?

MR. FOWLER: Object to the form of the question. It assumes facts not in evidence and is based upon a faulty premise.

A. I would have to see the point in question, sir.

Q. Well, sir, tell me if you know how many people in the United States smoke cigarettes?

A. No one has an exact number, sir.

Q. All right. You have placed in your report

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that as of 1993 there are 46 million smokers and 46 million ex-smokers; is that correct?

A. That -- may I see my report?

Q. Sure.

A. Yes, sir, that's what it states in my report.

Q. Is that a true statement as we sit here today in 1997, sir?

MR. FOWLER: Object to the form of the question.

A. With all respect, no one knows the exact amounts.

Q. All right. Are you a member of the American Psychiatric Association, sir?

A. Yes, sir.

Q. And are you a member in good standing of that association?

A. Yes, sir.

Q. And do you follow the rules, regulations, guidelines of that association?

A. I follow the rules and regulations.

Q. All right. You have a code of ethics, do you not, in that association?

A. Yes, sir.

Q. And do you -- are you familiar with the code

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of ethics of the American Psychiatric Association?

A. I've read them.

Q. All right. How many pages are there?

A. I don't know.

Q. When was the last time you read them?

A. Last several years.

Q. All right. Do you know if the ethics of the American Psychiatric Association require you to give accurate information when you are rendering opinions or reports in a case involving disputed facts of litigation?

MR. FOWLER: Can we hold on. Read that question back to me, please.

(The pending question was read by the court reporter.)

MR. FOWLER: Object to the form but you can answer that if you understand the question.

A. You'll need to break it down or restate it in some way.

Q. No, sir. I don't think I need to break it down. The question stands. You either answer it or don't, say you don't know or . . .

MR. FOWLER: But if you don't understand the question, if it's too complex, you

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can ask him to rephrase the question if you don't understand it. As he asked you at the beginning of the deposition, if you don't understand a question, you can ask him to rephrase it, unless he's changing his mind.

THE WITNESS: Okay. Could you repeat that, please.

(The pending question was read by the court reporter.)

MR. FOWLER: Same objection. You can answer the question if you can understand it.

A. I understand it. The American Psychiatric Association asks us to give facts to the best of our knowledge as the facts are available to us.

Q. The information you rendered in that report concerning smokers and nonsmokers was as of 1993; is that correct?

A. I so stated in this report as of 1993. There is no question in this report that my numbers were based on estimates based in the year 1993 and I so state it.

Q. And that is not the most accurate information in this case?

MR. FOWLER: Look, I'm going to object

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to this line of questioning. You should know that that's the most current information from the U.S. government, 1993. If you can produce more current information, go ahead and produce it. But that's the most current information from the U.S. government that I'm aware of.

MR. BECNEL: Okay.

MR. FOWLER: Are you aware of anything more current than that from the United States government?

MR. BECNEL: Absolutely.

MR. FOWLER: Okay. Let's see it.

BY MR. BECNEL:

Q. Are you familiar with the American Psychiatric Association Practice Guidelines, Practice Guidelines for Treatment of Patients with Nicotine Dependence, sir?

A. Yes, sir.

Q. Are you familiar with that document?

A. I read it.

Q. And that was published in and accepted for publication in July of 1996, was it not?

A. That is correct.

Q. And in reading that information, was there any

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statistical data concerning the number of smokers and nonsmokers in the United States?

A. There was an estimated statistical datum.

Q. And what was that estimated statistical data?

A. I don't remember that datum because it is just an estimate.

Q. Well, can you show me in this report, sir, and I will -- do you have a clean copy, Tom? Is it not a fact, sir, that in this report, which I will mark Exhibit 3, and I have a 2 already pre-marked and that's why I'm jumping.

MR. FOWLER: Okay.

Q. And ask you to look at page five of the report under Epidemiology and Natural History.

MR. FOWLER: Do you have another copy?

MR. BECNEL: That's the only one I have -- oh.

MR. FOWLER: We're talking about page?

MR. BECNEL: Five.

Q. All right. Under C, Epidemiology and Natural History.

A. Yes.

Q. What does the document say, sir?

A. "At present, approximately 50 percent of the

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United States adult population have never smoked, 25 percent are current smokers (48 million), and 25 percent are ex-smokers, reference 11."

Q. All right. Look at number 11, sir.

A. I have it.

Q. All right. And . . .

A. It's a Giovino GA, Henningfield JE, Tomar SL, Escobedo LG, Slade J, Epidemiology of Tobacco Use and Dependence from the Epidemiology Review 1995, 17:48-65.

Q. Do you feel that the association of which you are a member would give inaccurate information in its guidelines?

MR. FOWLER: Object to the form. This 1995 publication that's referenced, number 11, doesn't say what years that they're estimating that from, I mean . . .

Q. You can answer.

A. First of all, if it was published in 1995, the research was probably done in 1993 or 1994. I am much published in American Psychiatric Association journals and there is a lag time. Lag time entailing the research, lag time in doing the statistics, lag time in writing, lag time in

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acceptance and lag time editorial.

Secondly, the -- you asked me does the American Psychiatric Association publish anything inaccurate. The American Psychiatric Association, when reviewing articles, and I am a reviewer, assumes accuracy. It does not check. It does not -- reviewers are not required to go over initial data. It's not required. Only one reviewer is required to review statistical data, raw data. So the American Psychiatric Association cannot give an opinion as to accuracy or inaccuracy.

Q. Doctor, isn't it a fact . . .

A. I'm not done.

Q. Okay.

A. To say otherwise would be a misstatement. Thank you.

Q. Isn't it a fact that this document looked at a computer search from 1996 through 1995 on both PsycLIT and MEDLINE to get that information?

A. Of which document are you referring?

Q. The entire document that's before you, Exhibit 3.

A. Are we talking about the Escobedo . . .

Q. The entire document that is before you,

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Exhibit 3.

A. Please let me finish my question, sir. Are we talking about the Escobedo document or are we talking about the Practice Guidelines?

Q. The Practice Guidelines and the Escobedo document since it's included as a footnote to the document.

A. Then may I have the Escobedo document if we're going to refer to it?

Q. Just answer the question, sir.

A. If you . . .

Q. You're here to answer questions and that's what I'm giving you a question, you either answer it yes, no, don't know, don't understand. You can answer it.

A. I am trying to.

MR. FOWLER: Wait a minute. Wait a minute. If he has a question . . .

MR. BECNEL: No, he's not allowed to ask questions.

MR. FOWLER: If he has a question about the nature of your question, he's entitled to seek clarification. If he thinks he needs documents to answer your question accurately, he can ask for that

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information. If you don't have it, you can tell him he can answer the question to the best of his ability.

A. For clarification, to discuss intelligently the Escobedo document, I would request, respectfully, that you give me a copy of the Escobedo document so that I may respond to your questions regarding Escobedo.

Q. Okay. Now you can answer the question.

MR. FOWLER: Well, if you can. If you can't answer the question . . .

A. Do you have the Escobedo document or not?

Q. You can answer the question, sir. My question to you, as posed, you can answer.

A. Okay. I cannot answer Escobedo unless you give me a copy of this document or any document in there.

Q. You just told us, sir, that you didn't think people reviewed it. Were you aware . . .

A. I did not say that.

Q. Were you aware how many people reviewed the guidelines?

A. I did not say -- first of all, I think that was a mischaracterization of my previous testimony.

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What I said was when American Psychiatric Association reviewers review articles, we assume accuracy in terms of analysis of data and reportage of data. Plus only one reviewer is usually assigned to that statistical review, though we all may comment.

Q. Are you aware, sir, that 23 organizations and 76 individuals submitted comments prior to that report being published?

A. I am aware that there were a number.

Q. Were you aware, sir, that the search provided 675 relevant treatment articles?

MR. FOWLER: If you're referring to something in the document, you might refer the doctor to that, out of fairness.

MR. BECNEL: Well, he said he was familiar with it. I don't think I have to refer him to a particular place if he's familiar with the document.

MR. FOWLER: This is not a memory test, Doctor. Doctor, it looks like he's reading off of page one. Out of fairness, I'll tell you if he won't. It looks like he's reading out of the section called Development Process.

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A. JAMES GIANNINI, M.D.

MR. BECNEL: Counsel, you have taken probably half the time of this deposition objecting. And I would agree with you if we're going to do this deposition by 3:00, then if we continue in this manner we're not going to have the agreement that you want. Okay?

MR. FOWLER: Just treat the witness fairly.

MR. BECNEL: I'm treating him very fairly. I've given him a document which is before him and I'm asking him straightforward questions. You have an objection to every question we've asked, almost.

MR. KLEIN: That's because they're objectionable.

MR. BECNEL: Okay. You can answer, sir.

THE WITNESS: Could you repeat it.

MR. BECNEL: Miss Reporter, repeat the question.

(The pending question was read by the court reporter.)

A. The description development process says produced 675 development articles. That's the

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statement.

Q. All right. Did you make a computer literature search in rendering an opinion in this case?

A. I continuously make computer searches to stay up to date with the knowledge in the field of psychiatry.

Q. Unresponsive to my question.

Did you make a computer literature search in reference to this case, sir?

A. I think my question stands.

Q. You did or you didn't?

A. I make computer searches. Did I do one, an additional one for this case, no, it would be redundant.

Q. So you did not?

A. No. It would be redundant.

Q. All right. What time did you put on this case on your billing record, sir, for computer searches in connection with this case?

MR. FOWLER: Well, object to the form.

Q. All right.

A. I do not bill for computer searches because I do not have to pay for them.

Q. All right. Why do you not have to pay for

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them, sir?

A. I am a member of a hospital which is part of a medical school.

Q. And they have a computer record that generates time when using MEDLINE or PsycLIT, does it not?

A. It may.

Q. Well, do you know that, sir?

A. I do not know.

Q. What hospital did you use to make searches on, sir?

A. I use Youngstown Osteopathic, of which I'm a member, and St. Elizabeth Hospital, which one of my staff was a member.

Q. Give me the years in the last two years that you've made literature searches at either of those hospitals, sir?

A. Youngstown Osteopathic is an ongoing process.

Q. What year?

A. 1997.

Q. All right. Other than that?

A. 1996.

Q. Okay. Anywhere else?

A. In this past two years?

Q. Yes.

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A. I believe Ohio State University Hospital.
Q. When?
A. I believe that would be either the end of '95 or the beginning of '96.
Q. All right. What were the key words you used to make your research?
A. I cannot remember because it changes from month to month.
Q. Well, what are key words in a tobacco case that you would tend to utilize to make searches?
MR. FOWLER: Object to the form of the question.
A. Nicotine, cigarettes, tobacco.
Q. Smoking?
A. Sometimes.
Q. All right. Did you, in fact, make searches using those key words?
A. I gave instructions for my office to make them and I assumed they were done.
Q. So you did not personally make those searches, did you?
A. That is correct.
Q. At no time have you personally made a search, have you?

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MR. FOWLER: Object to the form of the question.

A. Not since I've become an assistant professor, no, sir.

Q. All right. When was the last time you have used a computer search yourself on either PsycLIT or MEDLINE to make a search for articles?

A. When I was a resident.

Q. Are you familiar with the . . .

A. Excuse me. I think when I was a resident, we didn't have computers then. I think it was a little more, it was a hand project.

Q. Okay. Now, since you are familiar with those guidelines before you in Exhibit 3, do you follow those guidelines?

A. No, sir.

Q. Huh?

A. No, sir.

Q. Why don't you follow the guidelines of the American Psychiatric Association . . .

MR. FOWLER: Object to the form of the question.

Q. . . . for the treatment of patients with nicotine dependence?

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A. Because I do not feel, to the best of my knowledge, experience and education, that there exists a syndrome such as nicotine dependence.

Q. All right. I've noticed from your opinion, sir, so that you disagree with the mainstream of thought on this subject, do you not?

MR. FOWLER: Object to the form of the question. It's argumentative.

A. I find that to be an inaccurate statement so I would say no.

Q. All right. Well, since you do not agree with the American Psychiatric Association's Practice Guidelines for the Treatment of Patients with Nicotine Dependence, can you tell me what organizations in the field of psychiatric treatment do you agree with or what guidelines you agree with?

MR. FOWLER: Could you read that back.

(The pending question was read by the court reporter.)

MR. FOWLER: Object to the form. If you can understand that question, go ahead and answer it.

A. I don't understand the question.

Q. All right. Well, tell me, sir, in terms of

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societies that you belong to or are recognized in the United States, what other societies in the field of psychiatric educational groups have guidelines for the treatment of patients with nicotine dependence?

A. The American College of Clinical Pharmacology does not, and the Royal Society of Medicine, which I belong, does not.

Q. The Royal Society of Medicine is in England, is it not?

A. Yes, sir.

Q. Was any English publication used by the American Psychiatric Association in formulating its Practice Guidelines?

A. I would have to review the literature.

Q. So you're not sure?

A. I -- no, I'm saying I would have to review the literature.

Q. So you don't know?

A. That is correct.

MR. FOWLER: If you want to take a look at the references, go ahead.

Q. Well, if you look at -- what is called the Oxford Collaborative Trials Registry?

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A. Okay, what reference number are you, sir?

Q. I'm just asking you that question, sir, what is that?

A. The Oxford Collaborative is an ad hoc group that has become an ongoing group for various clinical trials. Beyond that, I have no familiarity.

Q. Where are they located?

A. I don't know.

Q. Are they in London?

A. I don't know.

Q. Is it a organization, sir, that is accepted throughout the European community?

MR. FOWLER: Object to the form of the question.

A. Accepted for what purpose?

Q. For any purpose.

MR. FOWLER: Object to the form of the question.

A. I'm not sure what you're asking.

Q. You're not sure, sir?

A. I'm not sure what you're asking.

Q. Okay. Have you objected to the American Psychiatric Association's Practice Guidelines?

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A. No.
Q. Have you written any articles, either pro or con, to their guidelines?
A. No.
Q. Have you published any articles, either pro or con, to their guidelines?
A. No.
Q. Are you familiar with the Supreme Court decision in Daubert, sir?
MR. FOWLER: Object to the form of the question.
A. I've read it.
Q. Did your counsel furnish you with information on the requirements under a Daubert hearing or a Daubert test to determine an expert's credibility?
MR. FOWLER: Object to the form of the question. You're calling for a legal conclusion. You're also searching for work product under Mr. Sheller's definition of work product.
Q. All right. You can answer, sir.
A. To the best of my memory, legal counsel did not discuss Daubert. And we are speaking of Daubert versus Merrell Dow?
Q. That's what we're speaking of. All right.

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Are you familiar with the standards?

A. I've read them.

Q. All right. Have you ever undergone a Daubert hearing in any case where you have testified, sir?

A. Not to the best of my memory and recollection.

Q. All right. Do you know what the principles in order to be accepted as an expert under the Daubert requirements you have to be able to fulfill?

MR. FOWLER: Object to the form of the question. You're calling for legal conclusions rather than expert testimony. This gentleman is designated as an expert on nicotine-related issues, not on legal issues relating to Daubert or admissibility of evidence.

Doctor, if you don't know the answer to any of these questions, you don't have to answer them.

A. Okay. I don't know the answer.

Q. All right. Do you have a theory that you have espoused in this case in your report or opinion that has been tested, sir?

MR. FOWLER: Object to the form of the question. What do you mean by tested?

Q. The definition that Daubert uses.

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MR. FOWLER: Well, he's already told you he doesn't know about Daubert.

Q. All right. You can answer.

MR. FOWLER: No, he can't. If you can't answer that question . . .

MR. BECNEL: Then you can tell him -- you can instruct him not to answer.

MR. FOWLER: I'm not going to instruct him not to answer.

MR. BECNEL: Yes, that's what you're doing, Counsel.

Q. Answer my question, sir.

A. Since I previously told you I do not have in my memory banks the Daubert criteria, I cannot further respond to something I told you I don't know.

Q. All right. Do you have expert theories that have been put to any peer reviewed panels concerning nicotine dependence, nicotine addiction?

MR. FOWLER: Object to the form of the question.

A. I don't believe I have.

Q. Nor have you been published after peer reviewed concerning your theory of nicotine

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dependence or nicotine addiction as outlined in your report; is that not correct?

MR. FOWLER: Object to the form of the question. He hasn't suggested he has in nicotine dependence or nicotine . . .

MR. BECNEL: Counsel, those are not proper objections and now you're cluttering this deposition.

MR. KLEIN: Excuse me. I think it would be easier for the court reporter and just common courtesy requires that you permit him to finish what he's saying and then he'll let you say what you want to say.

MR. FOWLER: The witness hasn't espoused any nicotine dependence or nicotine addiction theories on this record.

Q. You can answer.

A. I believe you said after. That would imply I'd actually submitted something that had been rejected. I have never submitted anything.

Q. All right. So no opinions that you have in this case have ever been peer reviewed and published, have they?

MR. FOWLER: Objection. That's

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misstating his testimony. He said that his own articles. He didn't say anything about other people's articles.

Q. All right. You can answer.

A. The theory of addiction and the criteria have been published throughout the world.

Q. All right. What, in reference to your theory and your opinion, are the known rates of error between your opinion and those espoused by the American Psychiatric Association Practice Guidelines?

A. They've never been tested so a rate of error cannot be discussed.

Q. Do you know whether the methodology that you used to espouse your theory or your opinion is generally accepted methodology by the American Psychiatric Association?

A. By this one organization only?

Q. Yes.

A. This -- regarding methodology, my opinion does not discuss methodology.

Q. So nothing that you say in this case has anything to do with accepted methodology; is that not correct?

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MR. FOWLER: Object to the form of the question. That's not what he said. You're asking him about his own publications, not about other people's publications. It could be perfectly consistent with his opinions.

Q. You can answer the question, sir.

MR. FOWLER: What you said is a trick question.

A. It would be incorrect.

Q. All right. Tell me what is correct?

A. Could you repeat the question, sir.

MR. BECNEL: Miss Reporter, repeat the question, please.

(The pending question was read by the court reporter.)

MR. FOWLER: Same objection. Go ahead and answer.

A. The criteria for addiction are accepted throughout the world. The criteria for addiction were accepted throughout the United States through 1988. They are still used in the literature for research purposes with the exception of nicotine. In my review, ongoing review of the literature, I have found that the criteria which I have listed and

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I have discussed are still applied in clinical and -- research and clinical articles published throughout the United States and other English-speaking countries.

Q. All right. Sir, I'm going to show you Exhibit 2, which is your Attachment A which has -- sets out your hourly rate, daily rate, and the various cases in which you've testified over the last number of years; is that correct?

A. I haven't seen it yet. (Witness reviews document.)

The Attachment A seems to be correct.

MR. FOWLER: Just to clarify, Exhibit 2 is both the Attachment A plus Dr. Giannini's CV?

MR. BECNEL: His CV, yes. They were attached together, that's why I included them together as one exhibit.

MR. FOWLER: That's fine with me.

Q. So we don't waste time, this is what was provided to me by your lawyers. I assume you provided it to him.

A. Yes. Up to page 17, certainly, yes.

MR. FOWLER: There's highlighting on that page 18. Was that your highlighting . . .

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THE WITNESS: No.

MR. FOWLER: . . . or page 19, I guess.

MR. BECNEL: It wasn't my highlighting either. That's how it was furnished.

MR. KLEIN: The question is do you agree with the highlighting?

MR. BECNEL: Well, if we make a copy of it, we can eliminate the highlighting.

A. I don't read every article.

MR. KLEIN: Just so the record is clear, we can admit that the highlighting was put on by someone other than counsel that are at the deposition.

MR. BECNEL: That's correct.

MR. KLEIN: And not by the doctor.

MR. BECNEL: Right. And the CV consists of 36 pages.

MR. FOWLER: Right.

A. Okay. Superficially this appears to be my curriculum vitae.

MR. FOWLER: I can straighten that out for you if you want me to.

MR. BECNEL: Okay, yes.

Q. What is your definition of addiction, sir?

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A. Addiction is a state in which an exogenous substance can displace primary drives.

Q. Have you ever looked at the definition of addiction in the Philip Morris Employee Guidelines on their drug abuse policies?

A. I don't believe I've ever been furnished with Employee Guidelines.

Q. All right. I'm going to show you as Exhibit 4, page number six, a copy of What is drug addiction? And Is there a difference between physical and psychological addiction?

MR. FOWLER: Page six?

MR. BECNEL: Six, yes, sir.

Q. Are you familiar with that definition?

MR. FOWLER: Go ahead and read it all. Take your time.

A. Okay. Yes, I'm familiar with this definition.

Q. All right. Do you agree with that definition?

A. It's incomplete but I would agree with what's stated.

Q. All right. Why is the definition incomplete in the Philip Morris document, sir?

A. It omits such concepts as intoxication and the concept of tolerance.

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A. JAMES GIANNINI, M.D.

Q. Did you have occasion, sir, to write a book recently on drug abuse?
A. Yes, sir.
Q. What was the name of that book?
A. My most recent would be Drugs of Abuse, Second Edition.
Q. All right. Is this a copy of that book?
A. Yes, sir.
Q. When was it written?
A. I believe I completed it in October of 1995.
Q. And who requested you to write this book?
A. The publishing staff at PMIC.
Q. And what is the publishing staff at PMIC?
A. I'm not sure. It's a staff of people.
Q. Where?
A. At PMIC.
Q. Well, what is PMIC? That's what I asked you.
A. Oh, that's my publishing house.
Q. So you own your own publishing house?
A. No, it's a publishing house for whom I work.
Q. Well, whom do you work for?
A. PMIC.
Q. What is the name of that company? PMIC stands for what?

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A. I -- it's their -- I don't know. I just write PMIC.

Q. All right. Were you paid an advance to write this book?

A. No.

Q. Do you receive royalties from this book?

A. Yes.

Q. This is the last major publication in terms of books that you've written?

A. No.

Q. What book have you written since then?

A. I'm working on another book on Drug of Abuse.

Q. It's not published yet, is it?

A. No, it's -- I'm still writing it.

Q. All right. So this is the last published book that you have written?

A. That's correct.

Q. Okay. Now, it says that you are a fellow of the American Psychiatric Association in this book; is that correct?

A. That is correct.

Q. And it says you are currently a diplomat candidate for the University of London in the United Kingdom; is that correct?

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A. That is correct.
Q. What is meant by that?
A. I am a candidate for receiving a diploma.
Q. When do you anticipate receiving that diploma?
A. Either '99 or 2000.
Q. Why do you have to wait so long to receive that diploma?
A. Because I cannot give it my full-time attention.
Q. All right. Are you board eligible to receive that diploma at this time?
A. That diploma is in English literature.
Q. Okay. Are you board eligible to receive that diploma at this time?
A. There is no board eligibility in literature.
Q. Okay. And what is the purpose for receiving this degree from London in literature?
A. I want to study English literature.
Q. All right. This has nothing to do with the subject for which you were retained in this case, sir, is it?
A. No, sir.
Q. Now, you are a former professor and vice president of psychiatry at Northeastern Ohio

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University, the College of Medicine; is that correct?

A. No, sir, that's vice chairman.

Q. Pardon?

A. You said vice president. I was vice chairman.

Q. Vice chairman. I'm sorry. Do you still hold that position?

A. No, sir.

Q. When was that position terminated?

A. It wasn't terminated. I believe I resigned in 1990.

Q. Well, I'm not trying to be coy with you. I assume that you left, and when I said terminated, when you -- the relationship ended. That's all I meant.

A. Yes.

Q. All right. Why did you leave?

A. Because I was also teaching simultaneously at Ohio State.

Q. All right. And where do you teach now?

A. Now I'm director of alumni schools committee at Yale University.

Q. Okay. Do you teach in the field of psychiatry?

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A. No, sir.
Q. So you do not actively teach psychiatry at any institution at this time; is that correct?
A. That is not correct.
Q. Where do you teach?
A. I teach at a teaching hospital of Ohio University College of Medicine.
Q. Where is that located?
A. The campus of which I teach is at Youngstown, Ohio.
Q. And how many people are in that college in the field of psychiatry?
A. Well, every medical student is required to take some psychiatry.
Q. How many students do you teach on a yearly basis in the field of psychiatry?
A. It can vary from as little as two or three up to fifteen, twenty.
Q. Now, it says that -- in this book that you are a corporate medical director of Chemical Abuse Centers, Incorporated; is that correct?
A. That is correct.
Q. What is that organization?
A. That is an innovative approach to treating

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addiction, an outpatient model that we've helped set up centers in the United States and the U.S. Information Agency has sent me to the Caribbean, Canada, Europe and the Mideast to set up similars based on that model.

Q. Well, when you wrote this book, and apparently this book was copyrighted in 1997, it says nothing about being in the United States, does it?

MR. FOWLER: Object to the form.

Q. It says "This program was adopted for use in Italy, Cyprus, Barbados, Slovenia, Macedonia, Croatia," etcetera. Isn't that true? Not in the United States?

MR. FOWLER: Object to the form.

Q. Isn't that true, sir?

A. Yes, sir.

Q. Why wasn't it accepted when it was published in 1997 in the United States?

MR. FOWLER: Object to the form of the question.

A. It was accepted.

Q. Well, why didn't it have in About the Author any information that it was accepted in the United States rather than only in these foreign countries?

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A. Because that's a publicity blurb written by someone in the editorial staff there and they just put in what seems the most dramatic.

Q. All right. There is a disclaimer in this book, is there not?

A. Yes, sir.

Q. Tell the Court what is the disclaimer in this book on Drugs of Abuse, Second Edition?

MR. FOWLER: If you need to refer to it to answer the question, go ahead.

A. May I have that book now?

Q. Well, no, I don't think you need to answer -- just tell me what is the disclaimer?

A. You don't think I need to answer?

Q. No, I don't think you need to read the book. I asked you what is the disclaimer in the book you wrote in 1997?

MR. FOWLER: If you want the book to answer the question, we'll wait until counsel hands you the book.

MR. BECNEL: No, sir. We don't have to wait. Okay. I asked him what is his disclaimer in the book.

MR. FOWLER: You've got it right in

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front of you.

MR. BECNEL: That's fine. I can have all the books I want in front of me. I'm asking him what is his disclaimer in his own book that was written in 1997 and you're telling me he can't answer the question?

MR. FOWLER: If you can remember it word for word, go ahead and answer the question.

Q. No, just answer it generally, sir. What is the disclaimer in your book?

MR. FOWLER: This is unfair. You're just hiding information from him. He's -- this is ridiculous. You want to conduct the deposition in this way, go ahead. If you can answer the question, go ahead. If you can't, you can't.

A. Well, your question is two inaccurate things. First, the book was not written in 1997, it was written in -- finished in 1995. Secondly, that's not my disclaimer, that is the publisher's disclaimer. The publisher puts a disclaimer in. I do not.

Q. Did you consider cigarettes drugs of abuse, sir?

A. I did not.

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Q. So you don't consider cigarettes to be able to be abused; is that correct?

MR. FOWLER: Object to the form.

A. I do not consider cigarettes to be drugs of abuse.

Q. Is it not a fact that in the book that you published you don't even discuss cigarettes?

A. To the best of my knowledge, that is a correct statement.

Q. In fact, you don't discuss nicotine, do you?

MR. FOWLER: Object to the form of the question.

A. It may be mentioned. There's no discussion.

Q. In fact, if you look up in your index, nicotine is mentioned no where, is it, in your index?

A. To the best of my knowledge, it's not included in the index; however, the index was not written by me.

Q. And do you consider nicotine a drug of abuse?

A. I do not.

Q. Why not, sir?

A. It does not meet the criteria for abuse.

Q. Are you familiar with Caselret and Dolls, the

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Basic Science of Poisons toxicology book which is the bible of toxicology taught at every medical school in the country?

MR. FOWLER: Object to the form of the question, the characterization of the text.

Q. All right. Are you familiar with that, sir?

A. It may be a bible but it's not a bible at Yale, it's not a bible at Ohio State, it's not a bible at Northeastern Ohio University's College of Medicine. It must be a different religion there.

Q. Are you aware that it is taught at Yale, sir, that the Caselret and Doll's book is used to teach medical students and toxicologists at Yale?

MR. FOWLER: Object to the form of the question.

Q. Are you aware of that, sir?

A. The way Yale is set up, we have no absolutely required books for medical students. We are given a list. We may choose among the list.

Q. Are you familiar with Sax Book on Toxicology, sir?

A. Let me say this: There are some individuals who can cite authors and books and articles. I've never had that gift as a student, I don't have that

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gift now. I just cannot make cites. So I . . .

Q. Are you familiar, sir, with Richard Lewis' books dealing with the toxicology of certain chemicals?

A. As I said earlier, I'm not one of those people who can just give a citation for every book and article.

Q. All right. In terms of cigarettes, sir, what are the chemical components of cigarettes that appear in most of the books dealing with toxicology that are known carcinogenic agents both in animals and in human studies?

MR. FOWLER: Object to the form of the question. This is beyond this witness' area of expertise.

MR. BECNEL: All right.

A. Since I do not hold myself out to be an oncologist or toxicologist or botanist, I don't feel I can meaningfully respond to your question.

Q. You're a medical doctor, sir?

A. Yes, sir.

Q. And you had to take toxicology?

A. Toxicology is not a required course at either the University of Pittsburgh or Yale University

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where I matriculated.

Q. All right. So you did not take any courses in toxicology; is that correct?

A. That is correct.

Q. And you don't even understand toxicology, do you?

MR. FOWLER: Object to the form.

A. That is not a correct statement, sir.

Q. All right. What do you know about toxicology, sir?

MR. FOWLER: Object.

MR. KLEIN: I'm going to -- excuse me. Let me object. This is well beyond anything that this witness has disclosed as to giving opinions about and, really, if you're talking about wasting time, we're really now tremendously wasting time.

Q. You can answer the question.

MR. FOWLER: I'm going to object to the form of the question as well. Calls for a narrative that could take hours to answer, perhaps.

Why don't you read the question back.

(The pending question was read by the court reporter.)

A. Toxicology is a branch of pharmacology which

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embraces pharmacological, biochemical, organic chemical, physiological and micro-biochemical areas of learning. It studies the effects of various substance obtained artificially from natural flora and natural fauna which produce permanent or temporary effects upon a living organism which may be disadvantageous to this organism, may be -- may disrupt the function of the organism, or it may disrupt the structure of the organism.

Q. Are you familiar, sir, with certain books that are considered treatises in the field of toxicology?

A. There are shelves of excellent books in the field of toxicology.

Q. Have you had an opportunity, sir, to read the Surgeon General's report of 1979 concerning preventable illnesses from cigarette smoke?

MR. FOWLER: Object to the form.

A. I've read every Surgeon General's report since '64 so I assume I've read that one also.

Q. All right. And do you agree or disagree that cigarette smoking is the largest single preventable cause of illness and premature deaths in the United States?

A. I don't have more than superficial training in

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epidemiology so I do not consider myself possessing sufficient expertise to respond to that question.

Q. So you do not agree or disagree with it, you just don't feel you're competent to answer the question? Is that what you're saying?

A. I . . .

MR. FOWLER: Object to the form of the question.

A. Competency is a psychiatric term so I would leave it I don't feel I possess sufficient expertise.

Q. Are you familiar with the Centers for Disease Control, sir?

A. I know of it.

Q. Have you ever worked there, participated in any studies there?

A. No, sir.

Q. Do you know how many people die each year in the United States from smoking, sir?

A. No, sir.

MR. FOWLER: Object to the form.

Q. Pardon?

MR. FOWLER: Object to the form of the question.

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A. No, sir.

Q. Do you consider the Centers for Disease Control to be an institution whose opinion you would respect in this country?

A. I respect the institution and I certainly give its opinions my attention.

Q. Are you aware that over a thousand people each day die from cigarette smoking?

MR. FOWLER: Object to the form of the question. Again, we're way beyond this witness' designated area of testimony and he's already denied expertise in this area. If you have to guess, don't answer the question.

A. I would be guessing.

Q. All right. Are you aware that 434,000 people each year die from cigarette smoking?

MR. FOWLER: Same objection.

A. I would guess and I have no way of confirming independently those results.

Q. Are you familiar with the World Health Organization?

A. Yes, sir.

Q. Do you respect their opinion?

A. In certain areas.

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Q. Are you aware that smoking causes 2.5 million deaths annually?

MR. FOWLER: Object to the form of the question. Same objection concerning expertise and designation.

A. I have no way of evaluating their data. I have no way of evaluating the data of an organization that has once condemned Zionism as a disease which needs to be treated. This is also a finding of the World Health Organization so there are political considerations with that group.

Q. Do you agree that if present smoking patterns continue that the yearly toll will be in excess of 10 million people by the year 2025?

A. I have no . . .

MR. FOWLER: Object to the form of the question. Same objection concerning expertise and designation.

Q. Okay.

A. I have neither raw data nor -- to those projections, nor do I have expertise to analyze the raw data.

Q. Do you consider that prevention and treatment of nicotine addiction must focus on individual as

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well as the environments that affect individual behavior?

MR. FOWLER: Could you repeat that.

MR. BECNEL: Would you read the question back.

(The pending question was read by the court reporter.)

MR. FOWLER: Object to the form of the question. And Doctor, if you want to take a look at that language, it might be helpful for counsel to show you what he's reading from.

MR. BECNEL: I'm not reading from anything, Counsel.

MR. FOWLER: You were just reading from that book.

MR. BECNEL: No, I'm not reading from anything. I'm just turning pages.

Q. You can answer the question.

A. The premise is based on the fact that addiction is accepted as being secondary to nicotine. My whole testimony is that nicotine addiction does not exist as a clinical entity.

Q. Have you done any studies on the various types of cigarettes?

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A. No, sir.
Q. Have you done any studies on any of the types of tobacco?
A. No, sir.
Q. Do you know the difference between various types of tobacco?
A. Only at most superficially.
Q. Do you know that different types of tobacco has different chemical components?
MR. FOWLER: Object to the form of the question.
A. I am aware that different types, whatever the technical term, has a difference in the ratio of the constituents.
Q. Are you familiar with oxides of nitrogen that are in cigarette smoke?
A. I'm not sure what you mean familiar.
Q. Well, do you understand what oxides of nitrogen are?
A. Yes, sir.
Q. Are oxides of nitrogen a known carcinogenic agent?
MR. FOWLER: Object to the form of the question again on expertise and designation. It's

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also vague because it doesn't say whether you're talking about human or animal carcinogens.

A. To answer that question, again, I have no expertise in this area other than what's learned in med school. I need to know the form in which an oxide of nitrogen is being applied. I need to know the form and the vehicle.

Q. Well, do you know what nitrogen dioxide is?

A. Yes, sir.

Q. Is that found in cigarette smoke?

A. It's reported to.

Q. Is it a known carcinogen?

MR. FOWLER: Same objection.

Q. It's in both humans and animals.

A. To my knowledge, it's, in humans, it's a risk factor.

Q. Is it a known carcinogen? Yes or no?

A. To my knowledge, it is a risk factor.

Q. All right. Are you familiar with nitrogen monoxide?

MR. FOWLER: Objection. I mean, this is so far beyond this witness' designated testimony it's ridiculous.

A. That is an incorrect name for a nitrogen and

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oxygen molecule. It's not called nitrogen monoxide.

Q. So you -- well, what is nitrogen monoxide, sir?

A. I believe you're speaking of nitrous oxide.

Q. What is nitrogen monoxide?

MR. FOWLER: Object to the form of the question. This is a waste of time.

MR. BECNEL: Counsel, if you think it's a waste of time, you are welcome to leave; okay? I didn't ask you to appear here. I asked the witness to appear.

MR. FOWLER: The way this is unfolding, I wish I could leave . . .

MR. BECNEL: Okay. Well, then, leave.

MR. FOWLER: . . . but I'm obligated to stay.

Q. Answer the question.

MR. KLEIN: There's no reason to be rude.

MR. BECNEL: Well, I'm tired of being told that a deposition can last three, four hours and that we're sitting here with every question we ask there's an objection and a speaking objection.

MR. KLEIN: If you would basically do

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what counsel who have been in the Philadelphia case try to confine their self to the opinions that the witness has given as opposed to asking about extraneous matters while you're here in our city, then maybe we wouldn't be in this situation. But there's really no excuse, sir, for the rudeness that you're showing to both the witness and counsel who's opposing you, and I kind of think it's not called for.

Q. All right. You can answer the question.

A. I really need that repeated after that.

(The pending question was read by the court reporter.)

MR. FOWLER: Same objection.

A. All I can tell you, with organic chemistry, it's a union of the -- of nitrogen atom and oxygen atom.

Q. All right. Are you familiar with the toxicology of low tar cigarettes, sir?

A. As I testified . . .

MR. FOWLER: Object to the form of the question.

A. . . . earlier, I do not hold myself out to be a toxicologist.

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Q. All right. Have you reviewed any of the toxicology data on cigarettes in formulating your opinion?

A. No, sir.

Q. Have you reviewed any of the articles dealing with the toxicology of cigarette and cigarette tobacco components and/or chemicals in formulating your opinion?

A. No, sir.

Q. Do you feel you can formulate an opinion on nicotine addiction without understanding the toxicology of cigarettes and related additives or chemicals added to cigarettes?

MR. FOWLER: Object to the form of the question. It's compound and assumes facts not in evidence.

A. I would need that broken. I can't answer a multiple question.

MR. BECNEL: All right. Read the question, ma'am.

(The pending question was read by the court reporter.)

MR. FOWLER: Same objection. If you can answer that question, go ahead.

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A. I would need it broken because I think there are three or four questions there.

Q. All right. Is nicotine distilled from burning tobacco?

A. There's a school of thought that it is distilled and dispersed in liquid micro-droplets.

Q. And is it carried on tar droplets in the vapor phase?

A. Tar and nicotine are carried in water droplets.

Q. And so it's not -- is it carried in the vapor phase?

MR. FOWLER: Object to the form of the question.

A. I need to know what is carried in the vapor phase?

Q. Tar.

A. Yes.

Q. Do you know, sir, if absorption is across the membrane in a nonunionized state?

MR. FOWLER: Object to the form of the question. It's -- you mispronounced a word so there's no way for him to answer that question unless he knows what you're talking about.

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Q. You can answer.

A. I'm not familiar with unionized as a chemical concept.

MR. FOWLER: He should have said ionized.

MR. BECNEL: I'm sorry, did I say unionized?

MR. FOWLER: Yes.

MR. BECNEL: Non-ionized.

THE WITNESS: Okay. Then I . . .

MR. BECNEL: Okay. I apologize.

THE WITNESS: Okay. Because I was trying to figure that. So I really need that over. I'm not wasting time, I was just trying to figure out what unionized was. I'll need a run back.

MR. KLEIN: Can we go off the record for one second.

VIDEOGRAPHER: 11:44, pause.

(A recess was taken from 11:44 to 11:54 a.m.)

VIDEOGRAPHER: We're back on the record.

BY MR. BECNEL:

Q. Sir, do you understand what's known as the

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American blend of cigarettes?

A. I've heard that term.

Q. What is your understanding, the American blend?

A. It's a blending of different tobaccos.

Q. Do you understand the acidity of the American blend as cigarette smoke, as smoke?

A. I understand that cigarette smoke has a pH of less than 7.

Q. Well, less than 7 makes it . . .

A. Acid.

Q. . . . normal?

A. Makes it acid.

Q. Acid, all right. And how does the human body excrete this acidic mixture?

MR. FOWLER: Object to the form of the question.

A. Well, the mixture is -- well, first of all, the mixture is not taken into the body. To take it in, one would have to inject the contents of a cigarette.

Q. How is the metabolism of nicotine accomplished in the human body?

A. Okay. By -- less than five percent is not

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metabolized at all. Other metabolism goes through the liver. There is a question of metabolism occurring into the kidneys, and that's, again, a question, may or may not. And then it can be excreted.

Q. All right. And what percentage is it excreted?

MR. FOWLER: Object to the form. What percentage of what?

Q. Of nicotine.

A. Nicotine or its metabolites are eventually -- nothing is ever a hundred percent so it would be 90-plus plus plus that's excreted.

Q. And can you tell me what role do lipids play in nicotine excretion?

A. Well, in excretion, compounds, to pass to various parts of the body need to be lipid soluble in some form or another.

Q. Does nicotine affect heart rate in any way?

A. It can.

Q. How?

A. It can, depending on the circumstances, it can slow it down or raise it.

Q. Does nicotine bind with any specific receptors

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in any way?

A. Yes, sir.

Q. And which ones are those?

A. Acetylcholine.

Q. And how does it affect the central nervous system?

A. Acetylcholine?

Q. Yes.

A. Okay. Acetylcholine . . .

MR. FOWLER: Hold . . .

MR. BECNEL: Wait, Counsel, you can't object in the middle of an answer. You can object before the answer but you can't object in the middle of the answer.

MR. FOWLER: Would you read back the question before he answers, then. I don't know what is being answered.

(The requested information was read by the court reporter.)

A. Acetylcholine is a simple neurotransmitter. It has several origins. It originates at the nucleus basalis, a Meynert, projects to the neocortex. It also occurs in the striatal bodies.

Q. Can you tell me if nicotine affects heart

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rate?

A. I believe I answered yes.

Q. All right. And how does it affect heart rate?

A. It can slow it down or occasionally increase the rate, or it can slow it down or increase the rate.

Q. Does it affect blood pressure?

A. It can.

Q. Does it affect skin temperature?

A. It can.

Q. Have there been numerous studies on all of those things?

A. Yes, there have.

Q. Have you reviewed those?

A. I've reviewed studies.

Q. And what is your understanding after reviewing those studies of the effect of cigarette smoke and nicotine on the human body?

MR. FOWLER: Object to the form. Over broad.

A. That it can produce effects on certain areas that are volumes of the body.

Q. Can you tell me what is nicotine's detrimental effect to the human body, as you understand it?

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MR. FOWLER: Object to the form. It's again outside his area of expertise.

MR. BECNEL: I understand.

MR. FOWLER: And beyond his designation.

Q. How about as a medical doctor, sir?

A. You're speaking from a psychiatric point of view?

Q. As a medical doctor, sir.

A. Oh, I'm sorry, I didn't hear that. Okay. To get into nicotine's areas on the body other than psychiatric I think is outside the scope of my expertise.

Q. Does the American Psychiatric Association have any comparison of nicotine dependence and other drug dependencies?

A. The Association as a whole does not. That was never voted upon.

Q. Do they have any commonalities of both theoretical and clinical relevance?

A. That was never voted on.

Q. Are you familiar with the studies in the 1988 report of the Surgeon General's dealing with nicotine addiction?

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A. I've read the report and I've read the studies which I could obtain.

Q. And do you agree or disagree with those studies?

A. Some I agree, some I disagree. Some don't require an opinion.

Q. Okay. Tell me which portions of the Surgeon General's report that you disagree with?

MR. FOWLER: Object to the form of the question.

A. There are hundreds and hundreds of studies. I just don't have an eidetic memory that I could remember each one.

Q. Well, I'm referring to the 1988 Surgeon General's report which is about a 600-page report. Have you read that report, sir?

A. Yes.

Q. And in reading that report, sir, do you disagree with the process that the Surgeon General's team of scientists, in arriving at their opinion, utilized?

A. Okay. Just to be clear, I thought the question was the articles contained it, but we're not talking about the articles anymore, we're just

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talking about the report.

Q. We're talking about the report.

A. Disregard my misunderstanding. Okay, the report, yes, I do disagree.

Q. So -- and what parts of the report do you disagree with?

A. I disagree with the process in which they have exactly -- almost exactly the same data as in the '64, and utilizing that -- those same data arrive at a completely different set of conclusions.

Q. Do you also disagree with their portion of the report and definition of the term nicotine addiction?

A. I disagree with their term of nicotine addiction.

Q. All right. Do you disagree with the American Psychiatric Association's definition of nicotine addiction?

MR. FOWLER: Object to the form of the question.

A. The American Psychiatric Association, which I'm a fellow, does not have a position. To have a position, we'd have to vote on it and -- as we did on areas of premenstrual syndrome, homosexuality.

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We did not vote on this.

Q. All right. Do you agree or disagree with their definition of nicotine addiction?

MR. FOWLER: Object to the form.

A. Whose definition?

Q. The American Psychiatric Association.

A. As I said, the American Psychiatric Association does not take a position because it was not voted on. If you would restate the question, I can answer.

Q. Have you reviewed DSM-III, III-R, IV?

A. Yes.

Q. Do you agree with their position on nicotine addiction?

MR. FOWLER: Object to the form of the question. They use the phrase nicotine dependence, not addiction.

A. Okay. To comment on that, it says in DSM-III, DSM-III-R, DSM-IV that these books are not designed to be used in legal proceedings and should not. So I've always taken the position I do not discuss the DSM's in any legal proceeding and I will not do so here.

Q. So you're telling me you will not discuss

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those books, nor do you have any opinion as to whether they're right or wrong; is that correct?

MR. FOWLER: Object to the form.

A. That's not what I said. I said -- I did not comment on whether I thought they were right or wrong. My position has been since I started reading those books, since they said they were not designed and gave cautionary statements, they should be -- not be used, and it gave the reasons, I have taken positions in multiple jurisdictions that I will not comment upon them and I will take that position here.

Q. Do you agree or disagree with the methodology used in reaching the opinions that DSM-III, III-R and IV espouse on nicotine dependence, on nicotine addiction?

A. As I said earlier, since there are cautionary statements in the DSM that they should not be used in legal proceedings, I am taking the position I have taken in multiple jurisdictions that I cannot, in good conscience, comment on them in this legal proceeding.

Q. So you have no opinion whatsoever on the methodology that they used?

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MR. FOWLER: Object to the form.

A. You do not know whether I have an opinion or not because as I said earlier, in line with the cautionary statements in all the DSM's, these books are not meant to be used in legal proceedings. I am cautioned not to use them in a legal proceeding and it is my feeling it would be unethical to do so. I have maintained this in multiple legal jurisdictions and I am so maintaining in this jurisdiction.

Q. But you've never had that opinion upheld by a court or disagreed with by a court in a Daubert hearing, have you, sir?

A. I have had this opinion upheld in Common Pleas courts and federal courts.

Q. Not under a Daubert hearing, though, have you?

A. I am not a legal scholar. I cannot address the issue whether it was a Daubert hearing or not.

Q. Do you know if DSM-III, DSM-III-R and DSM-IV has any acceptable rate of error in reaching their conclusions and opinions in the booklets that were published?

A. Because of the cautionary statements in the book you have in front of you, I do not feel that I can ethically respond to any questions regarding the

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DSM's.

Q. Do you feel that in DSM-III, DSM-III-R and DSM-IV that this book was peer reviewed?

A. Based upon the cautionary statements in the book to which you referred, I do not feel that I can respond in a legal proceeding since the book clearly states it's not designed nor -- and should be used with great caution, or in other parts says it should not be used in a legal proceeding.

Q. Have you utilized DSM-III, DSM-III-R and DSM-IV in categorizing your bills for patients that you have seen or treated under Medicare, sir?

A. That I can respond to. Yes.

Q. And do you follow the guidelines in DSM-III, DSM-III-R and DSM-IV when submitting bills to various state and federal governments, insurance companies, and particular programs that pay for psychiatric and/or drug dependence treatment?

A. To my knowledge, Medicare now, in our state, uses ICDA and does not use DSM.

Q. All right. Did you participate in any of the DSM booklets?

A. No.

Q. Were you asked to participate?

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A. Yes.
Q. And what did you say?
A. I thanked them. I was working on my first book. I was still a resident, and I needed to spend my spare time writing my first book.
Q. When was the first year you were retained by a tobacco company in tobacco litigation?
A. I have never been retained by a tobacco company.
Q. A law firm who represents a tobacco company?
A. I'm not sure what retained means. That's . . .
Q. Meaning that you were asked to do work under an hourly, daily rate where you would be compensated.
A. I see. I believe the year was either 1980 -- it's between 1987 and 1989.
Q. All right. You don't remember?
A. At this moment, no, but it's one of those three years.
Q. All right. And . . .
A. And it would be the latter part of one of those three years.
Q. And approximately how much time do you spend

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as a consultant examining patients or doing work for lawyers or tobacco companies?

A. For lawyers or tobacco companies or lawyers for -- I just didn't catch . . .

Q. Lawyers for or dealing with cigarette litigation, tobacco . . .

A. Something to do with cigarette. Okay. That varies. Sometimes months will go by and I'm not doing anything for lawyers.

Q. Approximately what percentage of your time is spent doing consulting working for law firms or cigarette companies or lawyers representing cigarette companies?

A. If I could go back for the whole ten years, it would be under five percent.

Q. All right. And what percentage of your income is generated from working consulting with lawyers, cigarette companies and the like?

A. I don't consult with cigarette companies but lawyers would be under five percent.

Q. When you submit a bill, who pays you?

A. The law firm.

Q. You have reviewed a number of confidential documents, have you not . . .

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MR. FOWLER: Object to the form of the question.

Q. . . . dealing with the cigarette litigation?

A. Yes, sir.

Q. And you have been furnished those confidential documents by whom?

MR. FOWLER: Object to the form of the question. I don't know what confidential documents are being discussed here.

Q. All right. You can answer.

A. The firm of Shook, Hardy & Bacon.

Q. Have you ever signed a confidentiality agreement, sir?

A. These, no, these documents are not confidential. They're the formerly confidential documents that I believe Dr. Henningfield discussed and then were referred to me.

Q. All right. And what documents are you talking about dealing with Mr. Henningfield?

MR. FOWLER: It was actually Benowitz, for the record.

A. Benowitz. I'm sorry. Project Hippo.

Q. Any others?

A. And a series of documents. I don't think they

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really have a title.

Q. All right. Did you ever sign a confidentiality agreement?

A. No, sir.

Q. Have you ever been requested to sign a confidentiality agreement?

A. No, sir.

MR. FOWLER: Object. Are you talking about with regard to these documents?

MR. BECNEL: I just asked him those questions, Counsel.

MR. FOWLER: Well, I object because it was vague and if you're asking . . .

MR. BECNEL: You can't object after an answer.

MR. FOWLER: If you're asking with regard to documents, that's fine. But if you want an accurate answer, you've got to ask an understandable question.

A. I -- my understanding, the context is still documents.

Q. All right. Where are the documents that you have been furnished with to review or look at, where are they maintained?

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A. In my home.

Q. And how long -- how many documents have you been furnished to review since beginning tobacco-related activities as a consultant?

A. You're talking about those confidential documents?

Q. Any document dealing with tobacco-related consultation, sir.

A. How many have I had?

Q. Yes, sir.

MR. FOWLER: Object to the form of the question. Documents is undefined. I don't know if you're talking about deposition transcripts or company documents or what.

Q. You can answer.

MR. FOWLER: If you understand the question.

A. My understanding is memos, research reports, I would say maybe a banker's box, banker's box and a half.

Q. And those are all maintained at your residence still?

A. Yes, sir.

Q. Have you destroyed any of those documents that

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were furnished to you by any of the law firms, tobacco companies or law firms and/or other experts working for the tobacco companies?

MR. FOWLER: Same objection concerning what documents means.

A. Again, my understanding is these are the documents referred to by Dr. Benowitz and, no, I still have them in my presence -- in my home.

Q. Okay. In the 1988 Surgeon General's report, an opinion was rendered that cigarettes and other forms of tobacco are addicting. Do you agree or disagree with that statement?

A. I would disagree.

Q. Do you disagree with the method in which the Surgeon General reached that conclusion?

MR. FOWLER: Object to the form of the question. Asked and answered.

A. Well, this presupposes that it was the Surgeon General. He -- the Surgeon General actually did none of that work.

Q. Assuming his staff and scientists on his staff did that work, do you disagree or agree with the method in which that conclusion was reached?

A. I disagree with the method the staff used.

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Q. What would be a better methodology to use to reach a conclusion of whether cigarettes are addicting or non-addicting?

A. Not to change the criteria in the middle of the study.

Q. Have you ever participated in a study for the Surgeon General?

A. Yes, sir.

Q. Which one?

A. I was chairman of the Rape Commission at the time this was being done. When the Rape Commission's congressional commission expired, I was then assigned to two separate ad hoc commissions at the National Institute of Drug Abuse, and about two years ago I was made a special reviewer -- or three years ago was made a special reviewer, again at the National Institute of Health, for review of projects -- projects, grants, etcetera, on depression. It has a long name but that's what it does.

Q. Do you consider nicotine to be a drug?

A. Drug is a word depending on the context in which it's used.

Q. Do you consider nicotine to be a drug?

A. Again, I'd like to answer but I need a

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context.

Q. No, you need to answer under my term, do you consider nicotine to be a drug, either yes or no?

MR. FOWLER: He's asking you to define the term.

Q. No, I don't need to define the term. Do you consider nicotine to be a drug?

A. Okay. You said under your term, but I don't know what your term is. That's what you just said.

Q. You need to answer the question, sir.

MR. FOWLER: If you don't understand it, you don't have to answer.

A. I don't understand it.

MR. FOWLER: Define drug . . .

Q. You don't understand whether or not nicotine is a drug or not?

A. No, what I said, very clearly, under what context are you using the word drug? And I will be glad to answer you. Give me a context.

Q. Use your book, sir, and tell me what is the definition of a drug in your book?

A. In context of this book, drug means any substance which is used for abuse.

Q. All right. Is nicotine used for abuse?

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A. No.
Q. Is nicotine used for pleasure?
A. Yes.
Q. Is nicotine capable of being overused to the point that it affects people's perception or ability to function?
A. No.
Q. Why not?
A. God didn't make nicotine that way.
Q. Have you ever been to a cigarette manufacturing facility?
A. Yes.
Q. Which one?
A. It was in Montenegro and I don't speak Serb or Croatian but it was in Montenegro halfway between Niksit and Titograd.
Q. Any others?
A. That's it.
Q. You've never been to an American cigarette manufacturing facility?
A. No, sir.
Q. Have you done any research on cigarettes and nicotine addiction?
A. Again, I don't accept that nicotine is an

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addicting drug.

Q. Have you done any research on nicotine?

A. Research meaning?

Q. Any kind of research, as used in the medical profession, as used in the American Psychiatric Association profession.

A. The drug nicotine or . . .

Q. Yes.

A. . . . chemical nicotine or pharmaceutical agent nicotine?

Q. Yes. Pardon?

A. On nicotine, no.

Q. Have you done any studies with people on smoking, sir?

A. Yes.

Q. How?

A. We had a small group, my research group, we had a small group of people who were smoking and we gave one group a placebo and -- an inactive placebo and another group doxepin.

Q. Who sponsored that study?

A. It was sponsored in-house.

Q. By whom? Who paid for it?

A. Our professional group.

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Q. What professional group?

A. James Giannini, Incorporated.

Q. All right. So it's your personal professional group?

A. There were at the time about 14 health professionals but it's not personal.

Q. Where did the money come from in that health professional group? Where did you get the money to pay for doing this research?

A. Our own income. We've set aside so much for research.

Q. How much money did you set aside for research?

MR. FOWLER: Object to the form of the question.

A. That was 12 years ago. I don't know.

Q. Other than that one time 12 years ago, how much did you spend on research since that time?

A. It varies from year to year.

Q. All right. Let's say in 1995, how much did you spend on research?

A. I would have to check our . . .

Q. So you can't give me an answer?

A. Only my office manager/accountant could answer

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that.

Q. In 1996, how much did you spend on research?

A. Again, only my office manager/accountant. . .

Q. 1997 thus far this year, how much did you spend on research?

A. I don't have financial data with me.

Q. Did you spend any money on research dealing with nicotine or cigarettes or smoking in the last three years?

A. No, sir.

Q. Pardon?

A. No, sir.

Q. All right. When you did your study on cigarette smoking, nicotine and the like, what methodology did you use that is accepted within the scientific community in your professions as a medical doctor and a psychiatrist that are generally accepted?

MR. FOWLER: Object to the form of the question.

Would you read that back for me. I didn't understand the question, I don't believe.

MR. BECNEL: I thought I was speaking Croatian.

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MR. FOWLER: You might as well have been on that one.

(The pending question was read by the court reporter.)

MR. FOWLER: Go ahead and answer if you can.

A. To the best of my memory and recollection, it was a double-blinded crossover study.

Q. All right. Was it prospective or retrospective?

A. Prospective.

Q. And was it peer reviewed?

A. Yes.

Q. By whom?

A. The staff of the -- of Neuroscience Abstracts.

Q. And was it published?

A. Yes.

Q. Where?

A. The Society for Neuroscience Abstracts.

Q. Other than that study, have you done any others?

A. Yes, sir.

Q. What others?

A. We replicated the design with a larger group.

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Q. When? What year?
A. Following year.
Q. And what year would that have been, about?
A. It probably was published somewhere between '85 and '87, the original -- the published study so the other one would be done the following year.
Q. Were you provided any equipment by tobacco manufacturers or their lawyers or their foundations?
A. No, sir.
Q. Have you ever been provided any equipment?
A. Not to my knowledge.
Q. Have you had any of your fees paid for attending medical or psychiatric education on a continuing basis by any law firms or tobacco-related industries over the years? And I mean airfare, CME cost, hotel accommodations and the like.
A. I understand. Not to my best memory and recollection.
Q. Okay. Do you agree that nicotine is a drug that causes addiction?
A. I believe nicotine is a pharmacologically active substance that does not cause addiction, does not.
Q. All right. Are you familiar with this book

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from Oxford Scientific Publications, sir, called Nicotine Pharmacology?

A. I've seen that book.

Q. All right. Is it accepted in the field -- is it accepted in the field of nicotine psychopharmacology?

A. I would say . . .

MR. FOWLER: Object to the form of the question.

A. . . . since it's such a small field, it is used. I don't think the field is large enough to say accepted or not.

Q. Do you agree with the methodology used in this book?

MR. FOWLER: Object to the form of the question. Lacks foundation.

A. Well, this is not an experimental book, per se, so I can't comment. It's the use of the English language, that's the only methodology to which I could comment in this type of book, and they do write English quite well.

Q. Are you aware that this book, in accepting the '88 Surgeon General's report, states that the 600-page report incorporated the contributions of 50

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scientists and more than 2,500 published scientific papers?

A. I may have been aware when I looked at it.

Q. All right. Are you aware that this book then stated that cigarettes and other forms of tobacco are addictive?

MR. FOWLER: Object to the form of the question.

A. I believe that was the feeling of the authors.

Q. You disagree with this book then?

MR. FOWLER: Object to the form of the question.

A. I disagree with that statement in the book.

Q. In the book. Do you agree or disagree that nicotine is a drug in tobacco that causes addiction?

MR. FOWLER: Object to the form of the question.

A. I do not believe nicotine can cause addiction, and drug depends on the context in which it is used.

Q. So you disagree with both the Surgeon General's report as well as this book . . .

MR. FOWLER: Object to the form.

Q. . . . in that statement; is that correct?

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MR. FOWLER: Hold on, Doctor. Object to the form. Out of fairness, you should show the witness a copy of the book that you're reading from so he can assess the . . .

MR. BECNEL: I just did.

MR. FOWLER: Where -- I mean, show him the language you're reading from is what I'm talking about.

MR. BECNEL: I just did. I thought he was looking at it.

THE WITNESS: No, I didn't . . .

Q. That nicotine is a drug . . .

A. Your eyes are better than mine. Thank you.

Q. That nicotine is a drug that causes addiction. Do you agree or disagree with that statement?

A. I disagree with that statement.

Q. Look at number three and read it so that I don't misstate it and tell me whether you agree or disagree with that statement?

A. You would like me to read it out loud?

Q. Yes, please. I think it would save time.

A. It says "The pharmacological and behavioral processes that determine tobacco addiction are

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similar to those that determine addiction to drugs such as heroin and cocaine."

Q. Do you agree or disagree with that statement?

A. I disagree with that statement.

Q. So you disagree with all three statements made both in the Surgeon General's report, the 600-page report, and in the book called Nicotine Psychopharmacology; is that correct?

A. To be more accurate, I disagree with these conclusions. I don't necessarily disagree with the entire book.

Q. Do you disagree with their methodology?

A. In -- I disagree with the conclusions -- well, which book are we talking about?

Q. This one now.

A. We're not talking about Surgeon General anymore?

Q. No, this one. We already covered Surgeon General.

A. In part. Some of their methodology I think is fine and some of it I do not.

Q. All right. What methodology do you disagree with?

A. Okay. It's been a while since I looked at

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that book. I would need to review it again.

Q. So you can't tell me here today what methodology you think would be more acceptable in the field of accurate scientific knowledge in your field of study?

A. No, that wasn't the question. The question you asked me is the methodology in this particular book and I said it's been a while since I read it. I read lots of books. I can't remember the types of methodologies used in every book. Some people can. I can't.

Q. Have you read the portion of this book that deals with nicotine addiction?

A. I may have.

Q. Do you recall whether you did or you didn't, sir?

A. I can say I may have. I skimmed every chapter. Whether I read that chapter I do not know.

Q. Do you agree or disagree with the people who had this part of the book peer reviewed in terms of any of their qualifications?

MR. FOWLER: Object to the form of the question. Assumes facts not in evidence. It's vague.

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A. One assumption I think is erroneous, with all respect, is there was never in that book that it was peer reviewed. In fact, very few multi-authored texts are peer reviewed. Having edited more than several books which are multi-authored texts, we don't peer review. The editor reviews and generally allows things to pass in a book that cannot pass in an article. In a book we allow opinions, philosophical and ideological points of view which we would not allow in an article. And I'm assuming since there is no caveat that this was peer reviewed that it was not, in fact, peer reviewed.

Q. Are you familiar with the new regulations concerning the carcinogenesis of animal studies as related to humans now?

MR. FOWLER: Object to the form of the question.

MR. KLEIN: Also objection. Beyond the scope of his report.

MR. FOWLER: And, exactly, beyond the scope of his expertise and report.

Q. You can answer.

A. I don't hold myself out to be an expert in oncology, so I'm not . . .

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Q. Okay. As a physician, is nicotine known to be mutagenic?

MR. FOWLER: Object.

A. Based on its action on surface proteins it is a risk factor in mutagenesis.

Q. In terms of the medical probability, is it more of a risk factor or less of a risk factor using that standard?

MR. KLEIN: Object.

MR. FOWLER: Object to the form of the question.

A. This would assume expertise in the statistical methodology, which I lack. So therefore, I cannot rate probabilities.

MR. FOWLER: When we get to an appropriate point, can we take a short lunch break?

MR. BECNEL: Why don't you do that.

MR. FOWLER: Is now a good time? Let's go off the record.

VIDEOGRAPHER: 12:31, pause.

(A luncheon recess was taken from 12:31 to 1:04 p.m.)

AFTERNOON SESSION

VIDEOGRAPHER: We're back on the

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record.

BY MR. BECNEL:

Q. Dr. Giannini, I am looking . . .

A. Excuse me, it's Giannini.

Q. Giannini. I apologize.

A. You gave it a French name.

Q. Okay. I'm looking at your opinions and you state that there is no credible clinical comparison between smoking addiction to cocaine, heroin and alcohol and cigarette smoking. Why do you make that statement, sir?

A. I make it on the basis of symptomatology, when one is intoxicated, and in the case of either heroin or cocaine, I make it on the basis of tolerance and the need to utilize ever increasing dosages as finances allow. And I make it on the basis of severity of withdrawal symptoms.

Q. All right. Is that an accepted methodology?

A. That is an accepted methodology.

Q. And what -- who basically would you consider peers in the field that would accept that methodology?

A. That methodology has been accepted in writing this book Drugs of Abuse and all -- just my ongoing

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scholarly research for writing or just personal education or lecturing. That methodology is applied in every situation, just about, in the English language except in the study of tobacco and its effects.

Q. All right. You also state that it is -- that cigarette smoking is a voluntary activity. Why do you say that, sir?

A. People knowingly make a decision to smoke. People knowingly and voluntarily make a decision to continue smoking. And people can and do make a decision to quit smoking.

Q. All right. Do you feel that marketing plays any role in the choosing of smoking and nonsmoking by individuals?

MR. FOWLER: Object to the form. Outside the area of expertise and designation of this witness.

A. I don't have any courses in advertising or marketing. I can't respond.

MR. KLEIN: I'd also like to object that none of the plaintiffs have testified in this case that they relied on any advertising in connection with their smoking behavior.

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Q. When you say smoking is characterized as a ritual, what do you mean by that?

A. Well, in smoking, a number of processes must be initiated. They must be initiated in sequence and they're initiated repetitively each time a person smokes, thus establishing the ritual.

Q. Do you consider tobacco to be universally accepted as a form of drug dependence in which nicotine is a critical abuse-producing agent?

A. I believe the use of tobacco involves many issues. It involves taste, ritual, tactile sensation, heat, smell, and a variety of other factors as well as pharmacological.

Q. Do you think personality has any influence on an individual to determine whether he's more prone or not prone to smoke?

A. Certainly personalities determine utilization of various activities and recreational occupational pursuits.

Q. What do you consider the key motivation for a person to determine whether he wants to smoke or not smoke?

A. I think the level of behavioral science is such that we have not been able to isolate a key

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determinant.

Q. Do you agree or disagree with the 1964 Surgeon General's report that people who tend to live faster and more intensively tend to smoke?

A. Well, there is some evidence that this might be true but it is not overwhelmingly proven.

Q. So you would disagree with that report of the attorney -- of the Surgeon General?

A. No, I wouldn't disagree. I think there is some evidence that that report may be correct, but it's certainly not subtle science.

Q. Do you think any of the reports since that time have become accepted science in terms of peer reviewed research?

MR. KLEIN: Object.

MR. FOWLER: Object to the form.

Surgeon General reports?

MR. BECNEL: Yes.

A. All right. I don't understand. When you say they become subtle science for peer review, I honestly don't understand.

Q. All right. In terms of the Surgeon General's report dealing with people who live faster or more intensely, do you feel that those two personality

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aspects of an individual has been proven by peer review scientific study from '64 to the present?

A. I think I understand you now. Certainly some articles and some research paradigms indicate that this may be true but, again, it's not been, at least my opinion, it's not been proven.

Q. Do you consider that people who have depression are more prone to smoking?

A. This, when you say depression, do you mean the symptom or the disease depression?

Q. Both.

A. All right. So we're saying people who are depressed for a variety of reasons and people who are depressed because they have a major depression?

Q. That's correct.

A. All right. Certainly there are some data which indicate that this might be true. There is a -- some data there seems to be an association, but we don't know if it's a dependent association.

Q. Are you aware that cigarettes is the most heavily marketed consumer product in the United States?

MR. FOWLER: Object to the form. Assumes a fact not in evidence. Also beyond the

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witness' expertise and designation.

A. I'm not sure whether that's an accurate statement or not. I can't comment.

Q. Are you familiar with the Federal Trade Commission?

A. I've heard of the Federal Trade Commission.

Q. Do you think that they have the ability to know what is spent on marketing?

MR. FOWLER: Objection. Lack of foundation.

A. I do not know the inner mechanics of the Federal Trade Commission.

Q. If I were to tell you that the Federal Trade Commission estimated that $3.25 billion was spent on marketing cigarettes, let's say in 1988, would you have any information to agree or disagree with that?

A. I couldn't independently verify.

Q. Do you know of any drug of abuse, including nicotine, that is marketed in that fashion?

MR. FOWLER: Object to the form of the question. Assumes facts not in evidence. In fact, assumes facts contradicted by the witness.

A. All right. I do not, as again, I'll restate, I do not feel that nicotine is a drug of abuse. It

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is generally accepted that alcohol is a drug of abuse, and alcohol is heavily marketed in all its forms throughout the world.

Q. Can you tell me whether or not psychologists have used models to determine whether people are more prone or not prone to smoke?

A. Some psychologists have used models, that is correct.

Q. Have you ever used models to make that determination?

A. No, sir.

Q. Are you familiar with any of the models that have been used?

A. I've read models.

Q. Pardon?

A. I've read them. I'm not sure if that indicates familiarity, but I've read of the models.

Q. Are you familiar with the Office of Smoking and Health?

A. To my knowledge, there -- such an office exists.

Q. Pardon?

A. Such an office exists, to my knowledge, within the American federal government.

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Q. Is that with the CDC, Centers for Disease Control?

A. I don't know. I just know it's part of the structure.

Q. Have you ever done any research into the Office of Smoking and Health of the CDC?

A. No, sir.

Q. Are you familiar with any of their articles that are published?

A. I believe . . .

Q. Or reports that are published?

A. Reports, yes, sir.

Q. Are you?

A. I've seen some report, it was published in the 90's by that office or something with a similar name.

Q. Did you see the report that the CDC published in 1991 that stated one out of every six or seven deaths in each year is a result of cigarette smoking?

MR. FOWLER: Object to the form of question. Again, it's beyond this witness' expertise and designation.

Q. Okay. You can answer.

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A. I don't know if I saw that. I've only seen one product from them and I'm not sure that's it or not.

Q. Are you aware of why people who know that there's a high risk of health effects associated with smoking don't stop smoking?

MR. FOWLER: Object to the form. Go ahead and answer.

A. Okay. Please state that again. I think I understand what you're saying but I need it again.

MR. BECNEL: Why don't you read it.

(The pending question was read by the court reporter.)

MR. FOWLER: Same objection. Go ahead and answer.

A. Go ahead and answer. These people make a decision based on facts which are unique to their personality, life experience and genetics, other factors.

Q. Does race play any role?

A. Racial composition seems to play a role.

Q. Ethnic composition?

A. Ethnic -- in America?

Q. Yes.

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A. Yes, ethnicity seems to play a role.
Q. And gender?
A. Gender seems to play a role.
Q. Has smoking been linked to rebelliousness, impulsiveness in adolescents in deciding to smoke or not to smoke?
A. The word before was valuelessness?
Q. No, I think I used impulsiveness.
A. No, the word before.
Q. Rebelliousness.
A. Rebelliousness.

MR. FOWLER: Object to the form and, in particular, the use of the word linked.

A. It's never been established. Linkage implies cause and effect. It's never been established there's a cause and effect. Is something going on? Maybe. Is there a relationship? Maybe. Do these groups who share these characteristics seem to smoke more often? Most studies, but that does not establish linkage.
Q. Does education or socioeconomic status play any role in those people who decide to quit or not to quit smoking?
A. After they've initiated?

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Q. After they've started smoking.

A. It seems to do so.

Q. So the more educated you are and the higher socioeconomic status you have in society, those people are more prone to be able to quit smoking than those with less of those qualities?

MR. FOWLER: Object to the form of the question. If you can answer the question, go ahead.

A. Actually, it -- we don't know if they're more prone. We know that based on life factors, determinants, that people of higher socioeconomic status or education make a decision to quit at a higher rate. That's all we can say given the data we now have available to us.

Q. What do you think influences that decision?

A. The things that influence this decision are life experiences, socioeconomic status, education, choice of an opportunity to indulge in a variety of alternative pursuits, ability to receive both calming and excitatory activities in other arenas.

Q. Are you familiar with stress and relapse in terms of people who attempt to quit smoking?

A. Stress is a concept. Relapse is a concept.

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Q. Are you familiar with that?

A. Yes.

Q. Do you have an opinion concerning stress in terms of its relationship to people who stop smoking or don't stop smoking?

A. Yes.

Q. What is your opinion?

A. My opinion is that people find smoking to be a useful activity at times of stress.

Q. Why is that?

A. Because depending on the stress and what particular effect of a cigarette is employed, cigarettes can be mildly calmative. Sometimes the stress is a stress towards what we call a production stressor, and tobacco has several useful characteristics. It can increase one's ability to retain and enhance a short-term memory. It enhances concentration and ability to fix or focus upon a certain datum.

Q. Do you feel that most people begin smoking before adolescence or at about adolescence? And using an age range 13 to 16.

A. Do I feel?

Q. Or does your research or your looking at the

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subject in terms of what you have studied lead you to any conclusions?

A. And when you say "begin smoking," you mean . . .

Q. Initiate the first cigarettes between 13 and 16.

A. Based on what I've read, a large number initiate their first cigarette in that age range.

Q. Is there any reason why younger people, 13 to 16, would begin smoking? What are the reasons, from your field of specialty, that they start smoking?

MR. FOWLER: Object to the form of the question. It may be outside, in some respects, this witness' area of expertise and designation, but go ahead and answer the question to the extent you can.

MR. BECNEL: And I'll limit it to his field of specialty.

MR. FOWLER: Okay.

A. This would be based on more of epidemiological studies. I really don't have enough training or education to respond.

Q. Can you tell me, sir, whether or not you know that there is more prevalence for that age group of males to start smoking or females?

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A. More prevalence, that's . . .
Q. Meaning the 13- to 16-year-old group, the first time they start to smoke cigarettes, is there a higher incidence of people who begin smoking in male populations or female populations?
A. Okay. Studies are confused. Initially it was males. There's some evidence to be it is now females but it's not conclusive. Other studies say the opposite.
Q. Are you familiar with the 1989 study by the U.S. Department of Health and Human Services at page 303 and 304 that says every year since 1977 the prevalence of daily smokers among female high school people exceeds that among males?
A. As I said earlier, many studies show that but not everyone agrees with it.
Q. Well do you agree or disagree with that?
A. I have not the training nor the resources to independently verify.
Q. Do you have any information concerning whether research data shows that women have lower rates of quitting smoking than do men?

MR. FOWLER: Could you read that back.

(The pending question was read by the

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court reporter.)

MR. FOWLER: Is that question as of the date of the publication of the book you're reading out of?

MR. BECNEL: As of any date.

A. That is probably impossible to answer because those studies use a variety of definitions, a variety of criteria. So they're really not comparable and you can't say one -- that's something that's difficult to -- difficult when you get into behavioral studies.

Q. Does nicotine addiction or cigarette addiction have anything to do with weight gain or weight loss?

MR. FOWLER: Object to the form of the question. It assumes facts not in evidence. In fact, facts are contradicted by the witness, and it also is compound asking two different questions.

Q. You can answer.

MR. FOWLER: If you can.

A. I have difficulty answering it because as I have testified, cigarettes are not addicting. Nicotine is not addicting. So the premise makes it impossible for me to respond to the question.

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VIDEOGRAPHER: Excuse me, Counsel. We need to take a break to change tapes. This completes tape number one.

(A discussion was held off the record.)

VIDEOGRAPHER: We're now back on the record. This commences tape number two.

BY MR. BECNEL:

Q. Do you believe that stress plays an important factor in determining whether a woman quits or doesn't quit smoking after making an affirmative opinion that she's going to try to quit smoking?

MR. KLEIN: Objection to the form. It's a hypothetical not in evidence.

A. Some people smoke to relieve response to life stressors. This relief is one of the factors causing people to make a conscious decision to smoke.

Q. Do one's peers tend to influence whether a person smokes or not smoke?

A. Is that a question?

Q. Yes.

A. Certainly ritualization and socialization are one of many factors. And peer -- peer response is part of a socialization factor.

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Q. Have you reviewed any studies dealing with people who try or attempt to quit smoking when a family member, husband or wife, continues to smoke?

A. Yes.

Q. What do the studies show in your field of specialty?

A. Well, it's partially predicated by ethnicity. There was an interesting study, they compared Greeks, Turks, Bulgarians and Romanians. Romanians and Greeks did well. Bulgarians and Turks did not. So it seems that ethnicity may be important.

Q. But does the factor that a person within one's family, and let's talk about the United States, one's family member continues to smoke while one tries to stop smoking, does that have any reason for success or failure rates of whether or not they quit smoking?

MR. FOWLER: Object to the form.

A. It seems to be a contingent variable. There are -- it is a variable, then there are other variables which impacts enough variables, as I understand research designs, are in play that it cannot be isolated.

Q. Have you ever heard of a model used called the

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Health Belief model?

A. I don't remember the label. I may have heard of the model.

Q. Are you familiar with the rates of smoking among Native Americans or Indians?

MR. KLEIN: Objection. To my knowledge, and I understand you just got into the case today, I'm not aware that any of the named plaintiffs are Native American in this case.

Q. Okay. You can answer.

A. I didn't memorize that, no.

Q. Do you know from your general knowledge, sir, whether there are higher rates of smoking between certain types of ethnic Americans?

MR. FOWLER: Object to the form.

A. It is my understanding that certain non-mixed ethnic groups have higher rates than other non-mixed ethnic groups.

Q. Do you know why that is?

A. Some hypotheses. No one knows.

Q. Have you done any studies concerning various ethnic groups in the Philadelphia area, Italians, Germans, Jews, Hispanics, Caucasians, African Americans? Have you had any familiarity with those

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various groups as to whether or not there is more prevalence or less prevalence of smoking among those groups?

MR. FOWLER: Object to the form. It's complex, a little vague to me. If you can understand the question, go ahead and answer it.

A. Okay. You changed the question as you restated it.

Q. Basically what I want to know is knowing that the population, and let's use, first of all, Philadelphia area, are you familiar with the population from the Philadelphia area in terms of its ethnic characteristics among populations who smoke and don't smoke?

MR. KLEIN: Objection to the form. How do you define Philadelphia area?

MR. BECNEL: Greater metropolitan Philadelphia.

MR. KLEIN: How do you define that?

MR. BECNEL: That's just what I did. The greater . . .

MR. KLEIN: What counties do you include in that area?

MR. BECNEL: Just what I said.

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MR. KLEIN: That's what I thought.

Q. The greater Philadelphia metropolitan area . . .

A. I have studied . . .

Q. . . . under its enumerated districts as called for under the Census Bureau.

MR. KLEIN: I would object to that because the greater Philadelphia area includes parts of New Jersey and Delaware . . .

MR. BECNEL: That's why I used the enumerated districts.

MR. KLEIN: Excuse me . . . which, as far as I know, is not part of this lawsuit.

MR. BECNEL: All right. That's why I used the enumerated districts.

MR. FOWLER: Do you know what the enumerated districts are?

THE WITNESS: No.

MR. FOWLER: I mean, I don't know how you can answer that question. If you think you can, go ahead.

MR. KLEIN: Let's go off the record for a second because I don't want to clutter the record.

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VIDEOGRAPHER: 1:33, pause.

(A discussion was held off the record.)

VIDEOGRAPHER: Please proceed.

BY MR. BECNEL:

Q. All right. Using the term city of Philadelphia, the boundaries of the city of Philadelphia.

MR. KLEIN: Then I'd object on the basis that that's not the class definition of this case.

MR. BECNEL: Okay.

A. In the past, I have done an ethnic analysis of approximately five years ago of the city of Philadelphia looking at all major white ethnic groups plus Asiatics general, Indian Asiatics, Native Americans, blacks, and mixed race.

Q. For what purpose?

A. Publication.

Q. For what purpose?

A. To write a book on ethnic psychiatry.

Q. All right. What did your book on ethnic psychiatry show?

A. My partner died so it never got written.

Q. Who was your partner?

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A. Robert H. Liselle.

Q. And so you were able to reach any conclusions with what you did as of the time?

A. No. He was diagnosed as osteosarcoma and, of course, that is a death sentence and he lost, of course, interest in the book.

Q. Okay. Do you have any information in the state of Pennsylvania concerning the same subject, do you have any research, data, personal knowledge?

A. Yes. In 1974 I worked for Dr. Liselle when he was my professor, and prior to my internship I was chief research assistant for the Pennsylvania Governor's Justice Commission Study on nonviolent sexual crime, and one of the things we looked at was the ethnic makeup of the Commonwealth of Pennsylvania.

Q. And what did that show, sir?

A. That showed that there were different attitudes towards nonviolent sexual activity as to whether it was viewed by different ethnic groups within the Pennsylvania family as to the appropriateness, morality and legality of nonviolent sexual behavior.

Q. Is there any difference between people who are

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employed or unemployed who smoke?

MR. FOWLER: Object to the form of the question.

A. How do you mean different?

Q. Is there any rates, percentage of populations who are employed as opposed to populations who are unemployed who have either a greater or lesser prevalence of smoking within that definition?

A. There seems to be.

Q. And what is -- what does it show?

A. It seems, and all data are not consistent, that unemployed have a -- smoke more cigarettes per day than employed, but this is not true for certain job classification, nor is it true for the semi-employed.

Q. Are you familiar with the United States Department of Defense concerning military personnel who smoke and don't smoke?

A. I'm familiar with the Department of Defense.

Q. Are you familiar with their studies on the prevalence rate of smokers and nonsmokers within the U.S. military under the Department of Defense?

A. I'm familiar with some studies.

Q. And is there any relationship between officers

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and enlisted personnel?

A. There's not a relationship between officers and . . .

Q. In terms of smoking prevalence.

A. Okay. There's a difference.

Q. What is the difference?

A. Officers tend to smoke less except for certain specialized officer groups.

Q. Do they tend to be able to quit easier than does enlisted personnel?

MR. FOWLER: Object to the form of the question. I don't know how he would know what's easier and what's more difficult in that class. But if you can answer the question, go ahead.

A. The few studies that cover that showed that officers make a decision to quit and that there are factors to reward officers for quitting but there are not factors that reward enlisted men. In fact, this study was then repeated in Denmark and Norway. The Denmark study was then applied to NATO European troops showing officers quit because officers are rewarded both socially, in terms of promotion, in terms of command, staff command jobs which are necessary for promotion to the level of colonel or

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higher. This is basically what the study showed, the officers are rewarded for stopping smoking, whereas, enlisted men have no comparable reward structure.

Q. Are you familiar with the smoking prevalence in terms of percentages of adults aged 18 and older who smoke in Pennsylvania?

A. No, sir.

Q. Do you know approximately how many people, let's say in 1982, in Pennsylvania smoked?

A. Off the top of my head, no, I don't know.

Q. Do you know about what percentage of people in 1990 in Pennsylvania smoked?

A. I can say that I did not memorize the smoking percentages for any year.

Q. Do you have an approximate range of what percentage of the population smoked, let's say from the 80's to 1997?

MR. FOWLER: Again, for Pennsylvania?

MR. BECNEL: For Pennsylvania.

A. Since I don't know, I'd prefer not to guess.

Q. Do you know who keeps those statistics?

A. Yes. Approximate statistics are kept in Harrisburg. Also, a separate set of statistics are

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kept by some federal government agency also. There are two sets of stats.

Q. Are you aware that the Centers for Disease Control keeps those statistics?

A. It's some federal agency. I don't know which.

Q. Are you aware that the United States Department of Health and Human Services keep those statistics?

A. I'm aware that it's a government agency.

Q. Have you ever inquired of either of those departments as to the prevalence in terms of percentage of people who smoke in the state of Pennsylvania?

A. No.

Q. Do you know whether or not smoking has increased since the 1900's to the present time in the state of Pennsylvania or decreased in terms of percentages of population?

MR. KLEIN: Objection to the form. What's your start date?

MR. BECNEL: 1900.

MR. KLEIN: From 1900.

MR. BECNEL: To 1997 in terms of percentages whether it has increased or decreased.

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MR. FOWLER: Or increased and decreased.

MR. BECNEL: Or either way.

A. Based on research that I obtained through my Congressman, it is a multiphasic curve.

Q. And what does it show?

A. It's a multiphasic curve.

Q. Well, tell me, what does it show?

A. That, I just told you.

Q. Well, tell me what does it show in terms of decades, 1900 to 1910, 1910 to 1920?

A. There are periods of increase, periods of trough, another -- there are other periods of increase. There are at least three peaks and at least three troughs.

Q. And what statistical data that you have that you rely on that you know that that is peer reviewed or government accepted statistical data?

A. That came from my Congressman and it's from a government agency.

Q. What is it called? What government agency?

A. If I still have it, I would have to check.

Q. You don't have any information on it?

A. Yes.

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Q. I mean, you still maintain that information?
A. I may have it or I would just check with my Congressman from where was that obtained, or from his staff, not the Congressman himself.
Q. Have you ever reviewed the 1987 Economic Report to the President, Ronald Reagan, of the economic advisors in terms of its report on smoking?
A. No, sir.
Q. Do you know what it recommended?
A. No, sir.
Q. Were you aware that it categorized smoking as the greatest avoidable risk to the health and safety of American society than any other cause of death or disability in the United States?

MR. FOWLER: Object to the form of the question. Out of fairness to the witness, you should show him what you're reading from.

MR. BECNEL: Just what I said, the 1987 Economic Report to the President, Ronald Reagan, on his council of economic advisors.

MR. KLEIN: You saying it doesn't mean you're showing it to him. Thank you.

MR. FOWLER: You weren't reading from that study he was just referring to, you were

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reading from . . .

THE WITNESS: No, I just read the five-line quote.

MR. KLEIN: We should identify for the record what the witness was shown, the name of the book.

MR. BECNEL: He was shown a Medical and Public Health Implications of Tobacco Addiction.

MR. KLEIN: My only point is we should know the title of the book that appears for the . . .

MR. BECNEL: Well, you can do that. You can do that any time you want. When it's your turn, you can ask him what he read.

MR. KLEIN: I just think for the record it should be complete as to what you were showing the witness. Otherwise, the record won't be complete and we won't be able to know whether there's an appropriate objection to make for the judge to rule on. Now, if you're saying you refuse to say what book you just showed the witness, please say that.

Q. You can answer the question.

MR. KLEIN: Excuse me, sir, are you

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refusing to show -- are you refusing to identify for the witness what book you were showing him? I want the Court to be able to know that you're refusing to do that.

MR. BECNEL: Counsel, I quoted directly from the Economic Report to the President, Ronald Reagan.

MR. KLEIN: Well, I'm sitting in this room, sir, and you are not reading from that report, you are reading from a textbook in which I don't know what is in there. And if you won't identify what that textbook is, which may be hearsay or may not be, I think we're entitled to know what is in -- what book you're reading from.

Q. All right. You can answer the question.

MR. FOWLER: I mean, you can go ahead and answer the question with the understanding that counsel's concealing the identity of the book he's reading from and it's certainly not the report that he purports to quote.

A. Okay. And the question is now?

(The pending question was read by the court reporter.)

MR. FOWLER: Object to the form of the

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question for all the reasons previously stated. It's also hearsay and from an unidentified source.

Q. All right. You can answer.

A. To the best of my recollection and memory, I remember it being discussed in news magazines to which I subscribe.

Q. You've never read the report?

A. That is correct.

Q. Do you agree or disagree with the conclusions of what you read, that cigarette smoking was the greatest cause of injury and death in the United States from any other types of disease sources?

MR. FOWLER: Object to the form. It's not changing the question, it's eliminating key passages from the phrase and still just hearsay.

Q. You can answer.

MR. FOWLER: It's also beyond the experience and -- I'm sorry, the expertise and the report of this witness.

MR. KLEIN: And also it was asked and answered, many questions along that line, earlier.

MR. BECNEL: Counsel, up to this point I assume both of you represent the same defendant?

MR. KLEIN: No. You assume

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incorrectly, sir.

MR. BECNEL: Okay. Well . . .

MR. KLEIN: In part. And also, the Case Management Order says that two people may defend the deposition.

MR. BECNEL: I have no problem with two people but not two people making the same objections.

MR. KLEIN: I didn't make the same objections.

MR. BECNEL: To take time from a limited amount of time that we have because of the witness' schedule that I'm trying to complete.

Q. Okay. Let's answer the question.

A. Okay. Do I have an opinion based on -- that was your question, so we don't have to read it again?

Q. Yes.

A. Well, without actually reading a report, I'm not sure that I have -- well, first I don't know what the full report says and how they made their conclusions. Secondly, I'm not sure I have the expertise to comment on the report without reading it in its entirety.

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A. JAMES GIANNINI, M.D.

Q. As a medical physician and as a psychiatrist, do you believe that cigarette smoking causes lung cancer?

MR. FOWLER: Objection. Again, beyond the designation of the expertise of the witness. It's already been asked and answered, too, but go ahead.

A. Based on what I know, smoking may be a risk factor.

Q. All right. Do you believe as a physician and as a psychiatrist that it causes chronic obstructive lung disease?

MR. FOWLER: Same objection.

A. Say that again.

Q. Chronic obstructive lung disease.

MR. FOWLER: Same objection.

A. Based on what I know as a physician and my limited expertise in pulmonology and oncology, it may be a risk factor.

Q. Is it a risk factor in causing stroke?

MR. FOWLER: Same objection.

A. Based on my expertise, limited expertise in this area, it may be a risk factor.

Q. Is it a risk factor in causing cancer of the

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larynx, esophagus, and the oral cavities of the mouth?

MR. FOWLER: Same objection.

A. It may be a risk factor.

Q. In terms of medical probabilities, sir, is it more medically probable than not that it is linked to those diseases?

MR. KLEIN: Objection. Objection to the form. That's not the standard of proof in Pennsylvania, sir.

MR. FOWLER: Objection.

Q. You can answer.

MR. FOWLER: Could you read the question back, please.

(The pending question was read by the court reporter.)

MR. FOWLER: Object to the form of the question, particularly the use of the word link, undefined.

MR. BECNEL: You can answer.

A. A risk factor does not always imply or indicate linkage.

Q. I asked you if it's more medically probable than not that cigarette smoking causes cancer of the

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larynx, oral cavity and esophagus?

MR. FOWLER: Object to the form.

MR. KLEIN: Object to the form.

MR. DIETRICH: I'm going to object to that to the extent that it's beyond the scope of this case, that medical monitoring isn't being sought for that in this particular case.

MR. BECNEL: That's exactly what medical monitoring is all about.

MR. KLEIN: Well, let me . . .

Q. You can answer.

MR. FOWLER: Not in this case.

MR. KLEIN: Not in this case.

Q. All right. You can answer the question.

MR. FOWLER: If you can, Doctor, given your expertise and obviously being beyond your designation in this case.

A. I have no expertise in oncology and vascular treatment and very limited expertise in pulmonology, and I don't feel that it is sufficient to respond.

Q. Have you looked at any retrospective studies related to cigarette smoking and causes of cancer?

MR. FOWLER: Object to the form of the question. Beyond his expertise and expert report in

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this case.

A. I've looked at studies retrospective in which risk factors between smoking and cancer were investigated.

Q. All right. What were the conclusions reached in the studies you've looked at, that is, peer reviewed that is accepted by peer reviewed medical journals?

MR. FOWLER: Object to the form of the question for the same reasons previously expressed. Also, that question is compound.

Q. You can answer.

MR. FOWLER: If you can.

A. Some authors found a relationship. Not all authors found a relationship.

Q. All right. Are you familiar with secondhand smoke, sir?

A. In what context?

MR. DIETRICH: Objection.

Q. In any context.

MR. FOWLER: I'm going to object to the form of the question. This, again, is beyond his expertise and beyond the canon of this case.

MR. KLEIN: There's no claim relating

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to secondhand smoke in this litigation.

Q. You can answer the question.

A. Conceptually I'm familiar with secondhand smoke.

Q. Have you looked at a list of all of the various chemicals that are added to cigarettes that are distributed in the state of Pennsylvania?

MR. FOWLER: Object to the form of the question.

A. I've looked at a list of cigarettes that are distributed in the United States.

Q. All right. Have you looked at the list that are distributed in Pennsylvania?

A. I'm unaware that different chemicals are added to cigarettes in Pennsylvania than the rest of the United States.

Q. All right. Is benzene one of the chemicals you looked at?

A. Benzene is also naturally occurring in a number of vegetable products, including tobacco.

Q. All right. Is benzene a known carcinogen?

MR. FOWLER: Object to the form of the question. Beyond his expertise, beyond his expert report, and it's also undefined what kind of

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carcinogen, animal or human.

Q. You can answer.

A. To the best of my knowledge, benzene is a risk factor in contact, that is, actually touching benzene, or inhalation of extra large amounts.

Q. Is benzene known as a class A poison?

MR. FOWLER: Object to the form of the question.

A. I don't have sufficient expertise in toxicology to start classifying poisons.

Q. Is formaldehyde an ingredient in cigarettes and cigarette smoke?

MR. FOWLER: Object to the form of the question. It's compound. Are you talking about cigarettes or cigarette smoke?

Q. You can answer.

A. Formaldehyde is a natural product of -- occurring in many vegetables, including lettuce.

Q. Is formaldehyde a known carcinogen?

MR. FOWLER: Object to the form. Beyond his expertise. Beyond his expert report.

A. I still have insufficient expertise to respond to formaldehyde.

Q. As an expert, sir, when you have insufficient

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information, do you usually consult with other experts?

MR. FOWLER: Object to the form of the question. Vague and broad.

A. If it's needed to solve a particular problem, yes, sir.

Q. Have you consulted with any other experts in this case?

A. No, sir.

Q. Have you seen any medical reports other than the ones you've named in the deposition in the beginning concerning areas of toxicology?

A. Other than I used in my publications?

Q. Yes.

A. No, sir.

Q. You have made a statement that there is nothing inherent about smoking that prevents a person from comprehending and weighing the risks and benefits of smoking and making the decision to stop smoking or not to stop smoking; is that correct?

A. That is correct.

Q. On what do you base that opinion in terms of peer reviewed medical literature, sir?

A. I base it on a lifetime of education,

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training, residency, a career as a practitioner, as a busy practitioner and researcher with over 230 publications in the field of psychiatry and pharmacology.

Q. So you base it on peer reviewed articles or your own experience?

A. Both.

Q. What peer reviewed articles do you rely on in formulating your opinion?

A. Well, I read an average of three to four thousand peer reviewed articles every year of my life, more when I'm writing books. I can't single out.

Q. So you can't name at this deposition one peer reviewed article that you rely on; is that correct?

MR. FOWLER: Object to the form of the question. It's too broad. Are we just talking about this particular point?

Q. You can answer.

A. Okay. Because . . .

MR. FOWLER: Be specific in your answer.

A. Because of the large number of papers which I review, it becomes somewhat difficult to isolate one

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of tens of thousands of papers read in a lifetime.

Q. Can you tell me, sir, whether or not you have examined any patients in any of your previous association with lawyers, consultants or tobacco industry people since this started 10, 12, 15 years ago?

MR. FOWLER: Objection. It wasn't 10, 12, 15 years ago, and I think the question is vague. Are you talking about just tobacco litigation?

Q. You started working for them and you gave me a three-year period and you didn't remember exactly when you started working for them; is that correct?

A. "Them" being?

Q. The tobacco consultants or lawyers or the industry.

A. The lawyers. Never the industry. The lawyers.

Q. Okay. When did you start?

A. Roughly '87, a little later, '89.

Q. All right. Ten years ago?

A. Eight to ten.

Q. Eight to ten years ago. Can you tell me whether or not you have seen any patients in any of

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the litigation which you have testified?

A. No, I have not examined a patient.

Q. At no time in any of your consultation with these lawyers have you ever examined a patient; is that correct?

MR. FOWLER: Object to the form.

A. To the best of my recollection, that is correct.

Q. Is there any reason why you haven't, sir?

A. I was not asked to do so.

Q. Are you licensed in Pennsylvania?

A. Yes, sir.

Q. And you've been licensed in Pennsylvania since how long?

A. I would guess between '78 and '80.

Q. Do you actively practice medicine in Pennsylvania?

A. I'm not sure what you mean by actively practice.

Q. Well, consult patients, see patients.

A. I see Pennsylvania patients.

Q. How often?

A. When they drive to Ohio.

Q. And how often is that?

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A. Sometimes daily, sometimes I don't see them for a week.

Q. How many patients do you maintain in your active practice, sir?

A. That I see personally or the entire group?

Q. No, you personally.

A. I would guess over a thousand.

Q. And what percentage of the patients that you see are involved in litigation as opposed to non-litigation matters?

A. Under a tenth of a percent.

Q. Is involved in litigation?

A. That's correct.

Q. And what percentage of your practice is involved with research and writing as opposed to seeing patients?

A. Writing varies, depending on book schedules. Research, sometimes it involves patient care so they tend to overlap. So it's hard to, because taking care of patients may also be part of a research protocol.

Q. Have you ever been named in a malpractice case, sir?

A. I've been named.

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Q. How many times?

A. They've all been dismissed or withdrawn so I don't have the number, three, four.

Q. And what was the nature of the complaints against you?

A. In several of the cases I just happened to be the lawyer -- the lawyer, excuse me. I happened to be the doctor named because an intern, a nurse thought I was on the case. The lawyer looked at it, sent letters to everyone who was named on the chart, and then I was dropped out. I just -- I just was not involved in the case.

Q. When suits were filed by these individuals that named you, did they specify what you did in their complaint or their lawsuit?

A. Well . . .

MR. FOWLER: Object to the form.

Q. Or allegedly did?

A. Allegedly did. Well, in one case, a woman thought that she had an illegal incarceration. She -- how I got on it, she was scheduled to see me for Workman's Comp., had never seen me, I had never taken care of her, but she remembered my name so she put everybody's name, and the lawyer dropped that

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case.

There was another case in which a patient died at Ohio State University. I was not on the case, had not seen the patient. The patient had not been mine for many years. Every -- and I was just listed, had once seen Dr. Giannini. The family, the father who's a judge apologized that I was even included and I was dropped immediately.

There was another case, similar, a patient seen in another city, I had been the doctor many years ago. Again, dropped from the case.

Q. And those are the only three? I think you named three.

A. Okay. There's one more case, an interesting case, a fellow sued me, said I had not warned him of the side effects of a drug.

Q. What was the name of the drug?

A. Haloperidol. And I produced correspondence with the patient's attorney, copies were sent to the attorney, carbon copies of the letters I sent to the patient, These are all the side effects. Once the attorney said oh, yeah, these letters, he dropped the case, again, with his apology.

Q. All right. So that's the only four?

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A. That I can remember.

Q. All right. When was the last one filed?

A. The last one was filed I believe last year and dismissed immediately.

Q. Okay. Are there any pending against you at this time?

A. To my knowledge, none.

Q. Have you ever been reported to the medical society association or regulatory agency that deals with investigations of complaints by patients against physicians that's not a medical malpractice case?

A. Not to my knowledge.

Q. What . . .

MR. KLEIN: I'd also object. I mean, to the extent you're asking him about allegations, I'm sure you agree anybody can make allegations about anything.

MR. BECNEL: That's why I asked him that and I'm not implying anything for or against. This is a discovery deposition and I'm trying to find out . . .

MR. KLEIN: But it's got to be designed to lead to the discovery of admissible evidence and

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I think you're really going far afield with these questions and I object to them.

Q. Can you tell me, sir, whether you hold any patents?

A. Yes.

Q. What patents do you hold?

A. I hold a patent for use of Clonidine in the treatment of premenstrual syndrome.

Q. When did you obtain that patent?

A. I believe in the late 80's, maybe early 90's.

Q. Is it still a valid patent?

A. Well, I really don't look at it but the patent attorney told me that when it's about to expire and up for renewal, he'll notify me, so I assume it's still valid.

Q. All right. Do you receive any residuals or royalties as a result of that patent?

A. No.

Q. What was the purpose for which you designed that or obtained that patent?

A. It was designed to foster the use of this particular compound. The drug was already being manufactured generic, so I obtained a patent knowing that I would never obtain a royalty.

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Q. In terms of working, have you ever worked for any of the drug companies?

A. Pharmaceutical companies?

Q. Pharmaceutical drug companies.

A. Yes.

Q. Which ones?

A. SmithKline, I worked for their laboratory division. I worked for McNeil and the pharmaceutical division also at SmithKline. And on a short-term basis, Merck Sharp & Dohme, I believe.

Q. I have noticed that you have testified quite a bit in litigation; is that correct?

MR. FOWLER: Object to the form of the question.

MR. KLEIN: Object.

A. I don't think it's quite a bit.

Q. Well, in terms of your CV, without going through all of the times you've either been deposed or testified in a court case. Approximately how many times have you testified in an actual court case?

MR. KLEIN: At trial, you mean?

MR. BECNEL: Yes.

MR. KLEIN: As opposed to a deposition.

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MR. BECNEL: Yes.

A. It seems six.

Q. Six times in an actual court case?

A. At least in the past four years, yes, sir.

Q. Okay. And in the past four years, each time you have been tendered as an expert, tell me the field of expertise you have been tendered as.

A. In the Kurdilla, it was addiction.

Q. Addiction of what?

A. Cocaine.

Q. Okay.

A. In Morganstern, it was a compound case in a fitness for custody plus use of a steroid.

Q. All right.

A. Rogers, tobacco.

Q. All right. And what were you offered as in that tobacco case for Rogers?

A. Addiction expert.

Q. All right.

A. Malloy, I don't remember what Malloy was. Vrabel was a double murder with a specification, and I was, I believe, the Court's expert, either the Court's or the prosecution's expert, and the case was both insanity and competence. There were two

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separate issues. Rogers again. And I believe that's it.

Q. Have you ever been offered as an expert in criminal cases for either the prosecution or the defense?

A. Yes.

Q. How many times?

A. Under ten, I would guess.

Q. When was the last time?

A. In a criminal trial it would be October 2nd, 1995.

Q. And that dealt with what type of a case?

A. Double murder with a specification.

Q. And you were offered as an expert in what field?

A. They needed a general psychiatrist for competency and insanity. And I received the job because at the time I was chief medical examiner for the prosecutor's office for Mahoning County, Ohio, and that was my job. I wasn't offered, that was my job. I was the prosecutor's witness.

Q. Do you feel that there is any scientific link in terms of medical evidence between nicotine and various life-threatening disease processes?

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MR. FOWLER: Object to the form. Also beyond expertise and designation.

A. I can't -- I'd have to know internal medicine and epidemiology.

Q. Now, in terms of the reports you looked at, you told me, and I'm going to show you . . .

A. Which report, sir?

Q. Well, that's what I'm about to list for you.

MR. FOWLER: Pardon me for one moment. We've been going for about an hour. Can we take a short break when you get a chance?

MR. BECNEL: Go ahead right now before I start with this.

MR. FOWLER: Thank you.

VIDEOGRAPHER: 2:10, pause.

(A recess was taken from 2:10 to 2:20 p.m.)

VIDEOGRAPHER: Please proceed.

BY MR. BECNEL:

Q. Have you reviewed the medical reports of Timothy Michals on a number of the class reps?

A. Yes, sir.

Q. Were you given any of his notes or just his reports?

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A. His report.
Q. So you never looked at any of his notes?
A. That is correct.
Q. Have you looked at any of the medical records of any of the plaintiffs whatsoever?
A. Not to my best knowledge or recollection.
Q. The only thing you've ever looked at in reference to the plaintiffs, class representatives, are reports from other physicians?
A. That is correct.
MR. FOWLER: Object. Plus the depositions he referred to earlier.
MR. BECNEL: We already know that, yes. I'm not quibbling with that.
Q. You are familiar with the way they train people in medical school to look at medical records rather than just reports, are you not?
A. That is correct.
Q. You have not followed that procedure in this case of looking at people's original medical records, have you?
A. Now we're mixing two different areas. In medical school, which precedes my residency, I am looking at medical records for purposes of making a

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diagnosis. During my residency, the part of the residency that taught us forensic psychiatry we did, in some cases, utilize medical records. No, I'm sorry, we didn't utilize medical reports.

Q. How many people have you treated for cigarette cessation related problems?

A. Since I don't feel that's a medical problem, I do not treat it.

Q. So you've never treated anyone who came to you, say, Doctor, I'd like you to help me stop smoking?

A. I've never had a patient come to me with a complaint of, Doctor, I'd like -- I'm here to stop smoking.

Q. All right. Do you think that that is unusual among psychiatrists?

A. No.

Q. The only drugs that people have come to you to try to stop or be weaned off of have been what?

A. You'd like me to name them?

Q. Yes.

A. Very well. Alcohol, cocaine, cracked cocaine, phencyclidine, lysergic acid, diethylamide, dimethoxine, methamphetamine, amphetamine,

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methamphetamine, phencyclidine, phenyl-hexyl-pyrrolidine, alprazolam, diazepam, barbit- -- any type of barbiturates, I won't name them all. Ethchlorvynol, glutethimide, dimethyltryptophan, ketamine, mescaline, psilocybin, a mixture of it was moonshine, God knows what's in it, alcohol plus a lot of other things, and other drugs which are derivatives or chemically related to that list I just gave you.

Q. Have you ever utilized the Mayo Foundation's Nicotine Dependence Center patient questionnaire?

A. No.

Q. Have you ever utilized anyone's questionnaire for nicotine dependence?

A. No.

Q. Have, and I'm going to show you, let me spell this for you, Fagerstorom, F-a-g-e-r-s-t-o-r-o-m, a test for nicotine dependence?

A. I'm sorry, I thought you said you were going to show it to me.

Q. I'm sorry. Have you ever utilized . . .

A. I didn't realize that was a question.

Q. Okay.

A. No, I have not.

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Q. Do you know what it is?

A. Yes, sir.

Q. Is it an accepted tool to determine nicotine dependence?

MR. KLEIN: Objection to the form.

A. Okay. This is an interesting-scale. There's a strong literature, both for and against. Kozlosky when he was up in -- however it's pronounced -- in Toronto near Clark University at the Research -- Canadian Research Foundation for Drug Abuse, I'm not sure on the exact name, his group utilizes it, some other group utilizes, then there's this whole body of literature from the United States and Europe finding the Fagerstorom to be inaccurate, self-predicted, inconsistent. So it's controversial. Its major utility is it's self-predictive, self-fulfilling. However, it does have utility. If you're going to do a research project and you can use a scale that makes mistakes at the beginning and makes the same mistakes at the end, it's useful. So it's useful as a research tool. But as a clinical tool, it's a disaster.

Q. All right. So if the American Psychiatric Association tends to place credence in that, you

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would disagree with the credence that they place in it?

A. With all respect, that's an inaccurate statement. The American Psychiatric Association does not endorse this test or find this to be a credible test. Working groups within the association utilize it. But that doesn't mean that they have endorsed it. There are hundreds of tests out there that are used.

Q. How about the Mayo Foundation Nicotine Dependence Center patient questionnaire, do you think that that is a reliable tool to utilize to determine nicotine dependence?

A. It's a reliable tool to measure whatever it is the Mayo wants to measure. A lot of these tests are not -- see, I think there's a confusion on people who don't do research on a regular basis on what these tests do. They measure whatever it is you say they are measuring. It doesn't -- you can measure leprechauns and even if leprechauns do not or not exist, you can set up a credible tool to measure them and then you can say, well, the number of leprechauns in the Philadelphia metropolitan area has not increased since the mayor started cleaning

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the streets, and that would be, even though it's based on a fallacious premise, it's still a tool which has certain validity. But that does not make it accurate, it does not mean that there really are leprechauns for it to be a credible tool.

Having said all that, yes, the Mayo Clinic questionnaire is as useful as the Giannini/Becnel test for Philadelphia leprechauns, in that context.

Q. Have you ever designed a form to determine nicotine dependence or nicotine addiction or nicotine anything?

A. No.

Q. So in your entire career, sir, you've never treated people for nicotine addiction?

MR. FOWLER: Object to the form of the question.

Q. Is that correct?

A. As I said earlier . . .

MR. FOWLER: It assumes facts not in evidence and assumes facts contrary to the witness' testimony.

A. This would be like the leprechauns. Nicotine addiction, in my professional opinion, with

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reasonable medical certainty, does not exist.

Q. Nicotine dependence, have you ever treated anyone in your entire career for nicotine dependence?

MR. FOWLER: Same objection as previously.

A. Dependence is an overworked term and I don't feel it has any scientific validity anywhere because it's used by different groups to mean different things so it's not a useful clinical or -- at this time a useful clinical or research instrument.

Q. Have you ever used -- treated anyone who smokes too many cigarettes and wants to stop?

MR. FOWLER: Object to the form. Incomplete hypothetical.

Q. Children, women, adults, elderly?

MR. McCONNELL: Leprechauns.

A. I would need to know what too many meant.

Q. More than eight or ten a day.

A. Okay. And your question is?

Q. Have you ever treated anyone who says I smoke eight or ten cigarettes a day and I'd like to stop?

A. I have people who I treat for other real diseases and say I'd like to stop smoking.

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Q. But not one person in your entire career have you ever treated for just trying to stop smoking?

A. And I say that under oath, none, none have come to me with that presentation.

Q. All right. Have you ever prescribed, as a physician, nicotine gum, nicotine patches and the like?

A. I have prescribed nicotine gum.

Q. When?

A. Recently.

Q. How long ago?

A. I believe this summer.

Q. What was the purpose for it?

A. The patient said I'm going to -- I can't smoke at work. I don't want to chew tobacco. Can you prescribe nicotine gum for me?

Q. Other than that one patient, any others?

A. His wife.

Q. Other than that patient, any others?

A. Can't remember. That's not saying I didn't but I can't remember other than those two stick in my mind.

Q. Have you ever visited any programs that deal with smoking cessation?

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A. No.

Q. Have you ever visited any psychiatric hospitals that have been set up for nicotine dependence, addiction, or treating people that smoke too many cigarettes?

A. No.

MR. FOWLER: Object to the form of the question. You have to slow down to let me have a chance to object when necessary.

THE WITNESS: I see.

Q. Do you have any expertise in cessation programs?

A. In cessation programs?

Q. On nicotine dependence and nicotine addiction or smoking too many cigarettes.

A. Again, it's my . . .

Q. And I'm using that to try to -- in deference to your definition.

A. As I said earlier, nicotine addiction does not exist so it's difficult to have expertise in a nonexistent phenomenon.

Q. Is it not a fact that in each one of these class representative's medical reports, every one of them says they wanted to quit smoking cigarettes but

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they couldn't stop?

MR. KLEIN: Objection to the form.

MR. FOWLER: Object to the form.

Q. And I'm going to refer you now to Exhibit 5, which is the entire list of class representatives' medical reports from Dr. Michals.

MR. FOWLER: If you need to take a look through that to refresh your recollection.

MR. KLEIN: Can we see what you're showing the witness, please.

MR. BECNEL: It's your copy. It's your letter with copy.

MR. KLEIN: Okay.

MR. BECNEL: As it came to us.

MR. KLEIN: I just want to make sure because Miss Knisely said your side never got it and I'm glad to see that you did.

MR. BECNEL: I just got it.

MR. KLEIN: Okay.

MR. BECNEL: And I hope that it is accurate and correct and there are no alterations.

MR. KLEIN: That is just Dr. Michals' reports and the MMPI's that he administered.

MR. BECNEL: Yes.

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A. JAMES GIANNINI, M.D.

MR. KLEIN: Okay.

THE WITNESS: Excuse me, but the question once more?

(The pending question was read by the court reporter.)

MR. FOWLER: And you've handed it to him. What's the question now?

MR. BECNEL: I'm sorry.

A. That was a statement. That was not a question.

Q. Okay.

A. She quoted you as saying you're going to give this to me.

Q. I'm sorry.

A. I know there was something else.

Q. Okay. The question is, is it not a fact that in each of these medical reports from Dr. Michals that each of the people, the class representatives, stated that they wanted to quit smoking, many of them said they attempted to quit smoking, but that they all felt that they were addicted and couldn't quit smoking?

MR. FOWLER: Object to the form and if you need to look through that to make sure, go

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ahead.

Q. And I'm paraphrasing.

A. Only partially true, sir.

Q. Okay.

A. This is what they said. Ms. Salzman did, in fact, quit for three and a half years and resumed only because she was gaining weight.

Ms. McNally was able for a long period to limit her intake to 15 cigarettes only and did not make any -- demonstrate any attempt, a realistic attempt to quit but was able to modulate her intake based on what was her interpretation of the proper amount to smoke while on birth control pills.

Mr. Slivak did not follow through on any attempt.

Ms. Rodweller uses cigarettes to treat her headaches, has a reason to smoke, has not engaged in any credible attempt. She used acupuncture, was given a staple in the ear and pulled it out almost immediately after insertion and then smoked. She possibly used a patch and continued to smoke.

Mr. Barnes was involved in a family where just about everybody smoked, including his

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second wife. He made no effort other than stopping smoking without motivation when he was told -- felt that he needed to cut back to play the saxophone, he was able to make a modification. When he was approached using Nicorette gum, he refused to use it citing financial problems. And when he was told that there would be a trade-off, the cost of gum versus the cost of cigarettes, he dissimulated.

Ms. Potts opined that cigarettes were as addictive as heroin, cocaine, alcohol, as well as sex and money. She had not used any method nor engaged in any method to cut back her smoking saying only that a pill would just have to be invented and then she would. Okay. I think that's all.

Q. Is it generally true, Doctor, from your research and review of the literature, that most people attempt to stop smoking once they start?

MR. KLEIN: Objection to the form. I think the term attempt is vague.

A. We don't know really if people attempt. People say, more a majority say they made an attempt. But this, again, involves error. When we ask people things that are socially acceptable such as quitting smoking as socially acceptable, they

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will say yes. There's always great studies.

In Chicago when they were having the race riots, would you like to have a black neighbor, and three-quarters of the people in the area of Chicago surroundings said yes. But then the whole -- they voted for George Wallace and the neighborhoods went wild when blacks did try to move in.

People will say things that are socially acceptable to the interviewer. One must be careful in designing these studies. In most of the studies of which I've looked, there was no care taken into designing a study so that we can really evaluate this. So the answer would be some people say it, but do they. And the studies also have a flaw, and I'm not sure if they could even be fixed, what do we mean by a valid attempt. The studies are not consistent across the board and what defines the validity of such an attempt.

Q. Doctor, do you feel you have a medical ethical obligation to try to make your patients quit smoking?

A. No, sir.

Q. So you do not follow the AMA guidelines?

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A. The AMA guidelines deal with -- are first aimed at primary care physicians. I'm not a primary care physician. Most of my patients come to me upon referral of primary or secondary care physicians or osteopaths or chiropractors.

Q. Do you feel it is your obligation as a physician to try to improve the health of the population whom you treat and care for?

A. Yes, sir.

Q. When you see someone smoking of those thousand patients that are active patients of yours or that you consult with, do you tell them that they should quit smoking?

A. Well, I don't see anyone smoking. There -- no one smokes in my office.

Q. Well, when you take your history of the patient and family members, do you determine whether they smoke or don't smoke?

A. Yes.

Q. And when they do smoke, do you make a recommendation as a physician that they stop smoking?

A. When I see the patient, my first regard is the problem that brought them there, and that's what we

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treat.

Q. Do you smoke, sir?

A. No, sir.

Q. Have you ever smoked?

A. Never.

Q. Why did you not smoke?

A. Can't stand the smell and I think cigarette butts are disgusting.

Q. Okay. Do you think it's bad for your health?

MR. FOWLER: Object to the form of the question. Again, this is outside his area of expertise and his report.

Q. Do you think it's bad for your health, sir?

A. I don't know with reasonable certainty one way or the other.

MR. BECNEL: Thank you, sir. No further questions.

MR. KLEIN: Let's take a five-minute break.

VIDEOGRAPHER: We're now going off the record, 2:45.

(A recess was taken from 2:45 to 2:49 p.m.)

VIDEOGRAPHER: We're back on the

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record.

MR. FOWLER: Greg Fowler speaking on behalf of Lorillard and Brown & Williamson and we will reserve our questioning of this witness for trial.

MR. KLEIN: No questions.

MR. DIETRICH: No questions.

MR. McCONNELL: No questions from Philip Morris.

MR. STRAUB: No questions from Liggett.

VIDEOGRAPHER: This completes the deposition. We are now going off the record.

(Witness excused.)

- - -

(The deposition concluded at 2:49 o'clock p.m.)

- - -

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A. JAMES GIANNINI, M.D.

REPORTER'S CERTIFICATE

I, Dianna R. Pugliese, do hereby certify that the witness in the foregoing deposition was duly sworn to testify the truth, the whole truth, and nothing but the truth in the within-entitled cause; that said deposition was taken at the time and place therein stated; that the testimony of said witness was reported by me, a Registered Merit Reporter, and was thereafter transcribed under my direction into typewriting, and that this is a true and correct transcript of same.

I further certify that I am not counsel for nor in any way related to any of the parties to this suit, nor am I in any way interested in the outcome thereof.

Dianna R. Pugliese
Registered Merit Reporter
Certified Shorthand Reporter-NJ
Notary Public

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EXHIBIT

/

A. JAMES GIANNINI, M.D.

Dr. Giannini is a clinical psychiatrist specializing in the diagnosis and treatment of substance abuse. Since completing both a psychiatric residency and psychiatric fellowship at Yale University School of Medicine, he has been elected to memberships in numerous professional societies, and is a fellow of (among others) the American Psychiatric Association, the American College of Clinical Pharmacology, and the Royal Society of Medicine. Dr. Giannini is the author of several books and book chapters and numerous scientific articles on substance abuse. He has also taught psychiatry and conducted research. Dr. Giannini is currently the Medical Director of Chemical Abuse Centers, Inc.

Dr. Giannini will testify concerning the nature and definition of "addiction," the nature of cigarette smoking, and smoking maintenance and cessation. He may also critique the theories presented by plaintiffs' experts on the above subjects. It is anticipated that Dr. Giannini will testify that cigarette smoking fails to meet any classical scientific definitions of addiction, and that there is no credible clinical comparison between smoking and addictions to cocaine, heroin or alcohol. He is expected to testify that cigarette smoking is a voluntary activity, best characterized as a ritual; that smoking is a complex biological, psychological and social practice; that people smoke for many different reasons; and that the decision to smoke, and the decision to stop smoking, are personal decisions based on many factors, including genetics, education, life experiences, belief system, risk aversion, cultural background and other value system elements. Dr. Giannini is expected to testify that there is nothing inherent about smoking that prevents a person from comprehending and

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weighing the risks and benefits of smoking, making a decision to quit smoking, and/or carrying out that decision. He is further expected to testify that motivation is essential in the cessation of, and continued abstinence from, any pleasurable activity, including cigarette smoking; that the major determinant of successful smoking cessation is the personal decision and commitment not to smoke; and that professional assistance is not necessary to stop smoking. He is also expected to testify concerning the above topics as they relate specifically to the plaintiffs in this case.

Dr. Giannini is further expected to testify that no definition of "nicotine dependence" predicts anything about a person's ability to quit smoking; that smokers quit smoking all the time; that as of 1993, there were about 46 million smokers and 46 million ex-smokers in the U.S.; that the vast majority of these people quit on their own, without smoking cessation aids; and that there are millions of smokers who do not wish to quit and who have simply not made a decision to stop smoking. Dr. Giannini is further expected to testify concerning the neuropharmacologic effects of various substances of abuse, as well as other substances, including nicotine and caffeine.

Dr. Giannini may be asked to comment upon the opinions expressed by other witnesses in this case and the evidence upon which they rely, to the extent such evidence and opinions are within his area of expertise, specifically including, but not limited to, tobacco company research relating to smoking behavior. Dr. Giannini is further expected to testify concerning the nature and relevance of cotinine, a metabolite of nicotine, to human physiology.

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Dr. Giannini will base his testimony on (1) his skill, education, training, and clinical experience as a psychiatrist; (2) his knowledge of the scientific literature relating to smoking and to "addiction" and substance dependence;(3) his review of the plaintiffs' medical records, depositions and depositions of their family members; and (4) the testimony of plaintiffs' expert witnesses, the company documents they rely upon and additional testimony and documents as he deems necessary.

Please see attachment for further details concerning prior testimony, etc.

James Giannini 6-20-97

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EXHIBIT

2

DR. GIANNINI

ATTACHMENT A

Compensation for Study/Testimony

Study/Consultation:	$190/hour; $2500/day
Deposition Testimony:	$2250/day (in town); $3000/day (out of town)
Trial Testimony:	$3500/day

Trial/Deposition Testimony Within Preceding Four Years

1993	
September 30	Kovach, Trumbull County (Deposition)
1994	
June 15	Kurdilla, Stark County (Trial)
June 27	Morganstern, Trumbull County (Trial)
September 30	Murray, Summit County (Deposition)
1995	
February	Rogers, Indianapolis (Trial)
March 29	Fatimus, Mahoning County (Deposition)
August 30	Centofanti, Mahoning County (Deposition)
September 7	Vrabel, Mahoning County (Hearing)
September 21	Malloy, Mahoning County (Trial)
October 2	Vrabel, Mahoning County (Trial)
November 22	Baum, Mahoning County (Deposition)
1996	
April 10	Dash, Mahoning County (Deposition)
November 20	Cooper, Mahoning County (Deposition)
August 19	Rogers, Indianapolis (Trial)
1997	
February 5	Zuckerman, Mahoning County (Deposition)
May 30	Broin, Mahoning County (Deposition)

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CURRICULUM VITAE

A. JAMES GIANNINI, M.D.

Office Address
721 Boardman-Poland Rd
Suite 200
Boardman, Ohio 44512
(216) 629-2050
(216) 629-2056

Alternative Address
Chemical Abuse Centers Inc.
5211 Mahoning Avenue
Suite 110
Austintown, Ohio 44515
(216) 799-7677

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PERSONAL INFORMATION

Born: [DELETED] 1947
Youngstown, Ohio
USA

Citizenship: United States
Languages: English (Fluent)
German (Reading)
Italian (Reading)

EDUCATION

B.S.	...1970, Youngstown State University Youngstown, Ohio
M.D.	...1974, University of Pittsburgh Pittsburgh, PA
Internship	...1975, St. Elizabeth Medical Center Northeastern Ohio Universities College of Medicine, Youngstown, OH
Junior Residency	...1976, Yale University New Haven, Connecticut
Assistant Residency	...1977, Yale University New Haven, Connecticut
Chief Residency	...1978, Yale University New Haven, Connecticut
Clinical Fellow	...1978, Yale-New Haven Hospital New Haven, Connecticut
Diplomate Candidate	...1996, University of London, London, England

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EMPLOYMENT AND APPOINTMENTS (ACADEMIC)

1976-1978	...Co-founder and co-director, Wednesday Evening Clinic, Primary Care Center Yale-New Haven Hospital, New Haven CT
1976	...Acting Ward Chief, Connecticut Mental Health Center, Yale University, New Haven, CT
1978-1980	...Associate Director of Family Medicine in Psychiatry, St. Elizabeth Medical Center, Youngstown, OH
1978-1980	...Assistant Professor of Psychiatry Northeastern Ohio Universities College of Medicine, Rootstown, OH
1978-1990	...Member, Council of Chiefs in Psychiatry, Northeastern Ohio Universities College of Medicine, Rootstown, OH
1979-1988	...Senior Consultant for Training in Psychosomatic Medicine, Fair Oaks Hospital, Summit NJ
1979	...Chairman, ad hoc Committee on Student Probation, Northeastern Ohio Universities College of Medicine Rootstown, OH
1979-1981	...Member, Academic Review and Promotions Committee, Northeastern Ohio Universities College of Medicine Rootstown, OH
1979-1980	...Member, Human Sexuality Committee, Northeastern Ohio universities College of Medicine, Rootstown, OH
1980-1984	...Associate Professor of Psychiatry Northeastern Ohio Universities College of Medicine, Rootstown, OH
1980-1988	...Program Director, Department of Psychiatry, Northeastern Ohio Universities College of Medicine, Rootstown, OH

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EMPLOYMENT AND APPOINTMENTS (ACADEMIC CONT'D)

1980-1981 ...Member, Principles of Ambulatory Care Course Committee, Northeastern Ohio Universities College of Medicine Rootstown, OH

1980-1988 ...Member, Appointments Committee Department of Psychiatry, Northeastern Ohio Universities College of Medicine Rootstown, OH

1983-1989 ...Clinical Associate Professor of Psychiatry, Ohio State University School of Medicine, Columbus, OH

1984-1990 ...Professor of Psychiatry, Northeastern Ohio Universities College of Medicine Rootstown, OH

1985-1989 ...Chairman, Research Committee, Department of Psychiatry, Northeastern Ohio Universities College of Medicine Rootstown, OH

1985-1989 ...Vice Chairman, Department of Psychiatry, Northeastern Ohio Universities College of Medicine, Rootstown, OH

1986-1987 ...Member, Dean's Advisory Committee, Youngstown Campus, Northeastern Ohio Universities College of Medicine Rootstown, OH

1988-1989 ...Examiner, Department of Psychology, La Trobe University, Bundoora, Victoria, Australia

1989-1995 ...Clinical Professor of Psychiatry Ohio State University School of Medicine, Columbus, OH

1991 ...Member, ad hoc planning committee, "Recognition and Management of Drug Withdrawal," Department of Psychiatry, Ohio State University, Columbus, OH

1997 ...Panelist, Renaissance Weekend Hilton Head, SC

1997-present ...Area Director, Alumni Schools Committee, Yale University New Haven, CT

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EMPLOYMENT AND APPOINTMENTS (EDITORIAL & REVIEW)

1977-1982	...Member, Research Advisory Panel, Medical World News, New York, NY
1981-1984	...Reviewer, International Journal Psychiatry In Medicine
1982-1985	...Book Reviewer and Consultant, Medical Examination Publishing Company
1984-present	...Reviewer, Psychosomatics
1984-present	...Reviewer, J. Clinical Pharmacology
1984-1985	...Member, Research Advisory Board, Medical World News-Psychiatry Edition
1985	...Consultant, The Medical Letter
1985-present	...Reviewer, Psychiatry Research
1986-present	...Consultant, J. Biological Psychiatry
1986-present	...Reviewer, Clinical Toxicology
1987-present	...Reviewer, J. Clinical Psychiatry
1987-present	...Reviewer, J. Clinical Psychopharmacology
1987-present	...Reviewer, Neurobiology of Aging
1987-1988	...Member, Editorial Board, Clinical Laboratory Update
1987	...Reviewer, Ontario Mental Health Foundation, Toronto, Canada
1989-present	...Reviewer, American Family Physician
1990	...Reviewer, American Hospital Formulary Service: Drug Information
1991-present	...Reviewer, J. Personality and Social Psychology
1992-present	...Reviewer, Clinical Pediatrics
1993-present	...Reviewer, Perceptual and Motor Skills
1995-present	...Editorial Mentor, American Psychological Association
1995-present	...Reviewer, Psychological Reports

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A. JAMES GIANNINI, M.D.

EMPLOYMENTS AND APPOINTMENTS (GOVERNMENTAL)

1974	...Chief Research Assistant, Pennsylvania Governor's Justice Commission Study of Nonviolent Sexual Offenders
1979-1987	...Member of Board, Mahoning County Mental Health Board
1979-1984, 1986-1987	...Member, Ways and Means Committee Mahoning County Mental Health Board
1979	...Member, Project, Advisory Board "Role of Diet in Learning Disabled Children", Ohio Department of Mental Health
1980-1982	...Member, Citizen's Advisory Board, Woodside Receiving Hospital, Youngstown, OH
1981-1982	...Chairman, ad hoc Committee on Hospital Liaison, Mahoning County Mental Health Board
982-1984	...Second, Vice-Chairman, Mahoning County Mental Health Board
1983-1986	...Member, National Advisory Committee on Prevention and Control of Rape, Department of Health and Human Services, Washington, D.C.
1983-1984	...Chairman, ad hoc Committee on Inpatient Assessment, Mahoning County Mental Health Board
1984-1986	...Chairman, Mahoning County Mental Health Board
1984	...Acting Co-Chairperson, National Advisory Committee on Prevention and Control of Rape, Department of Health and Human Services, Washington, D.C.
1985-1986	...Chairman, National Advisory Committee on the Prevention and Control of Rape Department of Health and Human Services, Washington, D.C.

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EMPLOYMENTS AND APPOINTMENTS (GOVERNMENTAL CONT'D)

1985-1986 ...Member, Needs Assessment Committee of the Mahoning County Board of Commissioners, OH

1987-1988 ...Member, Youngstown Public Schools Community Curriculum Task Force of AIDS Sex Education and Teenage Pregnancy

1987 ...Member, Drug Abuse Clinical and Behavioral Research Review Committee National Institute of Drug Abuse, U.S. Department of Health and Human Services, Rockville, MD (Special Review Committee)

1988 ...Member, Site Review Committee National Institute of Drug Abuse, U.S. Department of Health and Human Services, Rockville, MD

1989-present ...Forensic Psychiatrist, Mahoning County Prosecutor's Office, Youngstown, OH

1990 ...American Participant (AmPart) U.S. Information Agency: Milan, Rimini, Palermo, Rome and Naples, Italy

1990 ...American Participant (AmPart), U.S. Information Agency: Nicosia and North Nicosia, Cyprus.

1990 ...American Participant (AmPart), U.S. Information Agency: Ljubljana, Skopje, Niksic and Zagreb, Yugoslavia

1992 ...American Participant (AmPart) U.S. Information Agency. Toronto, Canada

1992 ...Mentor, Gifted and Talented Students Program, Poland Middle School Poland, Ohio

1992 ...American Participant (AmPart) U.S. Information Agency. Bridgetown and St. Michael, Barbados

1992 ...American Participant (AmPart) U.S. Information Agency. Castries and St. Mary's, St. Lucia

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EMPLOYMENTS AND APPOINTMENTS (GOVERNMENTAL CONT'D)

1993-present ...Chief Forensic Psychiatrist, Mahoning County Prosecutor's Office, Youngstown, OH

1993 ...American Participant (AmPart)
U.S. Information Agency
Toronto, Canada

1993 ...American Participant (AmPart)
U.S. Information Agency,
Lucca, Italy

1994-present ...Member, Mahoning County Board of Mental Retardation and Developmental Disabilities (OH)

1995-present ...Member, Ethics Committee, Mahoning County Mental Retardation and Developmental Disabilities (OH)

1995-present ...Special Reviewer, Initial Review Group: Health, Behavior and Prevention Review Committee; National Institute of Mental Health, Rockville, MD.

997-present ...Treasurer, Mahoning County Board of Mental Retardation and Developmental Disabilities (OH)

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A. JAMES GIANNINI, M.D.

EMPLOYMENTS AND APPOINTMENTS (PRIVATE SECTOR)

1976-1978	...Associate Psychiatrist, Elmcrest Psychiatric Institute, Portland, CT
1980-1982	...Medical Advisory Board, Hospice of Youngstown
1981-1990	...Senior Consultant in Psychosomatic Medicine, The Regent Hospital, New York, NY
1981-1983	...Board of Directors, Good Samaritan Foundation of Youngstown
1983-1985	...Senior Consultant, Child and Adult Mental Health Center, Youngstown, OH
1984-1989	...Consultant, Smith-Kline Laboratories, St. Louis, MO
1984-present	...Medical Advisor, ProSport Inc.
1985	...Director of Psychiatric Services, Western Reserve Care System. (Northside Medical Center, Southside Medical Center, Tod Children's Hospital)
1985-1987	...Director of Toxicology, Western Reserve Care System
1985	...Member, Medical Executive Cabinet Western Reserve Care System
1985	...Acting Chairman, Department of Psychiatry, Western Reserve Care System
1985-1987	...Chairman, Department of Psychiatry Western Reserve Care System
1985-1986	...Member, Domestic and Social Policy Council, The Fund for an American Renaissance, Washington,. D.C.

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EMPLOYMENT AND APPOINTMENTS (PRIVATE SECTOR CONT'D)

1985-1987	...Member, Medical Executive Committee Western Reserve Care System
1986-1989	...Vice-Chairman, Health Committee, Youngstown Chamber of Commerce
1986-1988	...Chairman, Impaired Physicians Committee, Western Reserve Care System
1986	...Member, WYTV Eyewitness News Medical Advisory Board
1987	...Medical Director, Psychiatry and Toxicology Center, Western Reserve Care System
1987	...Member, Advisory Committee, Children's Galley, Butler Institute of American Art
1987-1989	...Director of Clinical Research Princeton Diagnostic Laboratories South Plainfield, NJ
1987-1988	...Chairman, Research Committee, Princeton Diagnostic Laboratories
1987-present	...Medical Director, Chemical Abuse Centers, Austintown, OH
1987	...Member, Impaired Disabled and Elderly Patrons Needs Assessment Committee, Butler Institute of American Art.
1987-1992	...Board Member, Advisory Board, Living in Grace Foundation, Youngstown, Ohio
1988-1992	...Board Chairman, Advisory Board, - Living in Grace Foundation
1988-1990	...Consultant, Neurodata, Inc. Los Angeles, California
1988	...Member, Scientific Advisory Board Neurodata, Inc.
1989-present	...President, Chemical Abuse Centers of Austintown

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A. JAMES GIANNINI, M.D.

EMPLOYMENT AND APPOINTMENTS (PRIVATE SECTOR, CONT'D)

1989-1995	...Co-Chairman, Health Committee, Youngstown Chamber of Commerce
1989-present	...Affiliate Member, The Cleveland Clinic, Cleveland, Ohio
1989-present	...Corporate Medical Director, Chemical Abuse Centers, Inc.
1990-	...Psychiatric Consultant, Second Chances Counseling Center
1992	...Medical Director, Lincoln Place Youngstown, Ohio
1994	...Testing Coordinator, American Guidance Service, Circle Pines, Minnesota
1995	...Member, Advisory Committee, Summer Arts Day Camp, Butler Institute of American Art

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A. JAMES GIANNINI, M.D.

HONORS AND AWARDS

1974 ...James Early Award In Clinical Psychiatry, University of Pittsburgh Medical School

1974 ...Upjohn Research Prize, University of of Pittsburgh Medical School

1976 ...Cited for Excellence in Teaching Medical Students by Department of Psychiatry, Yale University

1978 ...Honorary Tennessee Squire

1978 ...AMA Physician's Recognition Award

1978 ...Certificate of Appreciation, Medical World News

1979 ...Psychiatric, Psychogenic and Somatopsychic Disorders Handbook chosen as an alternate selection by Nursing Book-of-the-Month Club

1979 ...Fair Oaks Award

1980 ...Fellow, New Jersey Academy of Medicine

1980 ...Certificate of Appreciation, Medical World News

1981 ...AMA Physician's Recognition Award

1982 ...AMA Physcian's Recognition Award

1982 ...Certificate of Appreciation, Northeastern Ohio Universities College of Medicine

1982 ...Bronze Award, British Medical Association Film Competition, London, England

1983 ...Fellow, American College of Clinical Pharmacology

1983 ...Handbook of Overdose and Detoxification Emergencies, chosen as an alternate selection by Nursing Book-of the Month Club

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HONORS AND AWARDS (CONT'D)

1984 ...U.S. Jaycee Outstanding Young Men in America

1984 ...Certificate of Appreciation, South Carolina Medical Association

1986 ...Outstanding Leadership Award, Mahoning County Mental Health Board

1987 ...Recognition Award, Mahoning County Mental Health Board

1987 ...Certificate of Appreciation, Northeastern Ohio Universities College of Medicine

1989 ...Certificate of Nomination, Inc. Magazine; "Entrepreneur of the Year"

1989 ...Fellow, American Psychiatric Association

989 ...One-day Teaching Certificate Youngstown Public Schools

1990 ..."Silver Rose Award" Associazone Italiana Donnadori d'Organo (presented in Milan, Italy)

1992 ...Fellow, Royal Society of Medicine (Great Britain)

1992 ...AMA Physician's Recognition Award

1995 ...The Best Doctors in America
Woodward/White, Inc.
Aiken, South Carolina

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A. JAMES GIANNINI, M.D.

BIØGRAPHICAL LISTING

1974 ...Who's Who Among Students in American Universities and College

1981 ...International Who's Who Among Intellectuals

1983 ...Men of Achievement

1983 ...Marquis, Who's Who in Frontier Science and Technology

1983 ...Dictionary of International Biography

1983 ...American Men and Women of Science

1983 ...Personalities in America

1983 ...International Who's Who of Contemporary Achievement

1983 ...Community Leaders of the World

1983 ...Notable Personalities in American

983 ...The Directory of Distinguished Americans

1984 ...The International Directory of Distinguished Leadership

1984 ...Biography International

1987 ...Marquis, Who's Who in the World

1987 ...Marquis, Who's Who in Frontiers of Science and Technology-Second Edition

1988 ...Men of Achievement

1989 ...Marquis, Who's Who in the World

1991 ...Men of Achievement

1991 ...American Men and Women of Science

1992 ...Marquis, Who's Who in Science and Engineering

1992 ...Marquis, Who's Who in the Midwest

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BIOGRAPHICAL LISTING (CONT.)

1992 ...International Directory of Distinguished Leadership

1992 ...Dictionary of International Biography

1993-1994 ...Marquis, Who's Who in The World

1994 ...National Directory of Who's Who

1995 ...The Best Doctors in America
Woodward/White Inc.
Aiken, South Carolina

1996 ...Marquis, Who's Who in the World

1996 ...Marquis, Who's Who in Medicine and Health

1996 ...Marquis, Who's Who in Science and Engineering

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PROFESSIONAL MEMBERSHIPS

1973 ...American Medical Association

1978 ...American Psychiatric Association

1979 ...Academy of Psychosomatic Medicine

1979 ...American Academy of Clinical Psychiatry

1980 ...Fellow, New Jersey Academy of Medicine

1980-1981 ...Member, Member-In-Training Committee Ohio State Psychiatric Association

1980 ...Society for Neuroscience

1980 ...British Brain Research Association (Honorary)

1980 ...European Brain and Behavior Society (Honorary)

1981 ...World Medical Association

1983 ...Fellow, American College of Clinical Pharmacology

1983 ...American Association for the Advancement of Science

1984-1985 ...Member, Committee on Academic Psychiatry, Ohio Psychiatric Association. (Representative of Northeastern Ohio Universities College of Medicine).

1984 ...New York Academy of Science

1985 ...Sigma Xi

1985 ...Society of Toxicology

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PROFESSIONAL MEMBERSHIPS (CONT'D)

1988-present	...International Brain Research Organization (France)
1988-present	...Ohio Academy of Science
1989	...Fellow, American Psychiatric Association
1990	...Member, Steering Council, Ohio Chapter, American College of Clinical Pharmacology
1991	...Affiliate member, Royal Society of Medicine (Great Britain)
1991-1997	...Secretary/Treasurer, Ohio Chapter, American College of Clinical Pharmacology
1991-present	...Member, Executive Committee, Ohio Chapter, American College of Clinical Pharmacology
1992-present	...Fellow, Royal Society of Medicine (Great Britain)
1994-present	...Participant, American Psychiatric Association Research Network
1997-present	...President, Ohio Chapter, American College of Clinical Pharmacology

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Practice Guideline for the Treatment of Patients With Nicotine Dependence

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STATEMENT OF INTENT

This guideline is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns evolve. These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgment regarding a particular clinical procedure or treatment plan must be made by the psychiatrist on the basis of the clinical data presented by the patient and the diagnostic and treatment options available in the particular clinical setting.

This practice guideline has been developed by psychiatrists who are in active clinical practice. In addition, some contributors are primarily involved in research or other academic endeavors. It is possible that through such activities some contributors have received income related to treatments discussed in this guideline. A number of mechanisms are in place to minimize the potential for producing biased recommendations due to conflicts of interest. The guideline has been extensively reviewed by members of APA as well as by representatives from related fields. Contributors and reviewers have all been asked to base their recommendations on an objective evaluation of the available evidence. Any contributor or reviewer who has a potential conflict of interest that may bias (or appear to bias) his or her work has been asked to notify the APA Office of Research. This potential bias is then discussed with the work group chair and the chair of the Steering Committee on Practice Guidelines. Further action depends on the assessment of the potential bias.

This practice guideline was approved in July 1996 and was published in October 1996.

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Practice Guideline for the Treatment of Patients With Nicotine Dependence

American Psychiatric Association

PRACTICE GUIDELINE

I. INTRODUCTION

This practice guideline provides guidance on the care of patients with nicotine dependence. Cigarette use is the most common cause of nicotine dependence, and almost all of the data available are derived from studies of cigarette users; thus, this document will focus on cigarette smoking. The recommendations in the guideline generally apply to all smokers even though not all smokers meet DSM-IV criteria for nicotine dependence (1). This is because most of the principles for treating nicotine dependence apply to non-nicotine-dependent smokers as well. Many smokers have comorbid psychiatric conditions (2), which are not described in this guideline; thus, the psychiatrist caring for a patient who smokes should consider, but not be limited to, the treatments recommended in this practice guideline.

This guideline is intended for psychiatrists. However, the data summarized in this guideline should be useful to all clinicians caring for nicotine-dependent patients.

This guideline focuses on three groups of smokers likely to be seen by psychiatrists (table 1).

Concurrent with the development of the present guideline, the Agency for Health Care Policy Research (AHCPR) developed its *Clinical Practice Guideline on Smoking Cessation* (3). The AHCPR guideline focuses on primary care providers but also includes recommendations for smoking cessation specialists and health care administrators. The present guideline builds upon the AHCPR guideline by focusing on specific populations (table 1) not covered in the AHCPR guidelines. In addition, the APA guideline complements the AHCPR guideline in providing detail on the more intensive therapies. Psychiatrists interested in providing smoking cessation treatments should be familiar with the AHCPR guidelines (3).

This practice guideline is limited to recommendations for treatment. Actions to change public policy toward tobacco are very important to decreasing the prevalence of smoking and psychiatrists are strongly urged to support such actions. APA's *Position Statement on Nicotine Dependence* (4) lists the more important actions needed. These include: a) encouraging appropriate diagnosis and treatment of nicotine dependence as a comorbid condition with other psychiatric disorders; b) increasing state and federal taxes on tobacco products and applying the proceeds of such taxes to the prevention, treatment, and research of nicotine dependence; c) changing the warning labels on tobacco products to include the high likelihood of developing dependence on nicotine; and d) advocating for health insurance coverage of treatment of nicotine dependence by qualified health professionals.

TABLE 1. Target Populations

1. Patients who smoke and are being seen by a psychiatrist for a psychiatric disorder other than nicotine dependence or withdrawal
2. Smokers who have failed initial treatments for smoking cessation and need more intensive treatment that could be provided by a psychiatrist
3. Psychiatric patients who smoke and are temporarily confined to smoke-free inpatient wards, residential facilities, etc.

Prevention and treatment of smoking in young persons are also very important. This guideline focuses on adults. Modifications for treating adolescents are briefly discussed in section V.C.2. Psychiatrists are referred to *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* (5) for more information on preventing and treating adolescent smoking.

II. DEVELOPMENT PROCESS

This practice guideline was developed under the auspices of the Steering Committee on Practice Guidelines. The process is detailed in a document available from the APA Office of Research, the "APA Practice Guideline Development Process." Key features of the process included:

- initial drafting by a work group that included psychiatrists with clinical and research expertise in nicotine dependence;
- a comprehensive literature review (description follows);
- the production of multiple drafts with widespread review, in which 23 organizations and over 76 individuals submitted comments (see section VII);
- approval by the APA Assembly and Board of Trustees;
- planned revisions at 3- to 5-year intervals.

A computerized search of the relevant literature from MEDLINE and PsycLIT databases for all years available (i.e., 1966–1995 and 1974–1995, respectively) was conducted using the terms "cigarettes," "nicotine," "smoking," and "tobacco." No exclusion criteria were used. This search produced 675 relevant

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treatment articles. Other databases searched were the Center for Disease Control and Prevention's *Bibliography on Smoking and Health* (6), the Oxford Collaborative Trials Registry (7), and the bibliography of the AHCPR *Clinical Practice Guideline on Smoking Cessation* (3). In addition, references in empirical articles and narrative and meta-analytic reviews were used to locate articles.

For brevity, meta-analyses and reviews of treatments for smoking are usually cited in the guideline instead of original studies. However, the conclusions of the work group are based on knowledge of the individual studies included in these meta-analyses and reviews and on other pertinent studies.

III. EVIDENCE RATINGS

Each recommendation in the guideline receives one of three categories of endorsement using a bracketed Roman numeral following the statement. The three categories are based on the scientific literature and on clinical expertise and represent varying levels of clinical confidence in the recommendation. Three varying degrees of clinical confidence are noted:

[I] Recommended with substantial clinical confidence. These recommendations are usually based on several well-controlled clinical trials that reported similar findings or represent key principles of clinical psychiatric care with broad expert consensus.

[II] Recommended with moderate clinical confidence. These recommendations are usually based on a few positive studies or on less-consistent data from many sources.

[III] Recommended with lower clinical confidence or recommended on the basis of individual circumstances. These recommendations usually have not been adequately tested or have conflicting reports about efficacy but are consistent with expert opinion and with accepted principles of treatment of smoking.

I. EXECUTIVE SUMMARY

The following executive summary is not intended to stand by itself. The treatment of smoking cessation requires the consideration of many factors and cannot be adequately reviewed in a brief summary. The reader is encouraged to consult the relevant portions of the guideline when specific treatment recommendations are sought.

Recommended psychiatric management strategies that all smokers should receive are listed in table 7 (see page).

Table 8 lists the recommended treatments and their ratings (see page 7).

There are a number of promising treatments for nicotine dependence that may be recommended based on individual circumstances. These include intensive behavior therapy [III], educational/supportive groups [III], exercise [III], hypnosis [III], anorectics [III], antidepressants [III], buspirone [III], higher-than-normal dose transdermal nicotine [III], mecamylamine [III], nicotine inhaler [III], and sensory replacement [III].

Treatments that *cannot be* recommended at this time for the treatment of nicotine dependence (either because of data indicating lack of efficacy or lack of sufficient evidence supporting efficacy) include: contingency contracting, cue exposure, hospitalization, nicotine fading, physiological feedback, relaxation, 12-step therapy, ACTH, acupuncture, anticholinergics, benzodiazepines, β blockers, glucose, homeopathics, lobeline, naltrexone, nutritional aids, reduction devices, silver nitrate, sodium bicarbonate, and stimulants.

Psychiatrists should assess the smoking status of all their patients on a regular basis. If the patient is a smoker, the psychiatrist discusses interest in quitting and gives explicit advice to motivate the patient to stop smoking, including a personalized reason the patient should stop [I]. When possible, advice may come from multiple sources in addition to the psychiatrist; e.g., from other physicians, nurses, social workers, etc. [I]. Written materials may be used as well as face-to-face interventions [II]. Since many psychiatric patients are not ready to quit, the goal of advice will often be to motivate patients to contemplate cessation by reviewing the benefits of quitting, discussing barriers to quitting, and offering support and treatment [III]. If the patient is interested in stopping smoking, a quit date should be elicited, treatment prescribed, and follow-up arranged [II]. The minimal initial treatment for those who wish to quit includes written materials, brief counseling, and a follow-up visit or call 1–3 days after the quit date [II].

If the patient has failed serious attempts without formal treatment, failed with nonpharmacological therapies, had serious withdrawal symptoms, or appears highly nicotine dependent, transdermal nicotine is recommended [I]. If the patient prefers or if ad-lib dosing is needed, nicotine gum can be used instead of transdermal nicotine [I]. If used alone, nicotine gum is to be taken on an every-hour basis [I]. If the patient is a highly nicotine-dependent or heavy smoker, higher-dose nicotine gum should be used [I]. Nicotine gum can also be used on an ad-lib basis to supplement transdermal nicotine therapy [II].

If the patient has had trouble stopping smoking for nonwithdrawal reasons (e.g., due to skills deficits), he or she is a candidate for multicomponent behavior therapy [I]. The more effective components of behavior

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therapy appear to be skills training/relapse prevention; rapid smoking, in which patients inhale cigarette smoke every few seconds; and stimulus control strategies [III]. Some smokers also appear to benefit from group support [III].

Combined behavior therapy and nicotine replacement improves outcome over either treatment alone and is recommended when available and acceptable to the patient [I]; however, attending behavior therapy should not be a prerequisite to receiving nicotine replacement therapy [I].

For the smoker who has failed adequate treatment, as described previously, and who is interested in making another attempt to stop smoking, the psychiatrist should assess the adequacy of prior treatments and evaluate the patient for ongoing or residual alcohol, drug, or psychiatric problems that need treatment [II]. If the patient has previously failed an adequate trial of transdermal nicotine and relapse appeared to be withdrawal related, three options are reasonable: a) ad-lib nicotine gum added to transdermal nicotine [II], b) oral or transdermal clonidine [II], or c) nicotine nasal spray [III]. If relapse was due to reasons other than withdrawal (e.g., stress), multicomponent behavior therapy should be considered [I]. If the patient has previously attended such therapy, more intensive individual behavior therapy (e.g., 1–2 times/week for 2–3 weeks) should be considered [III].

Psychiatric and general medical patients who smoke and are on smoke-free wards should receive clear instructions about the no smoking policy, advice to stop smoking, and education about the symptoms and time course of nicotine withdrawal [III]. Those patients who wish to use the smoke-free ward to initiate a stop smoking attempt may receive the therapies outlined previously [I]. Patients who do not wish to stop smoking permanently and who evidence nicotine withdrawal may be instructed in behavioral strategies to decrease withdrawal symptoms [III] and provided nicotine replacement (patch or gum) [II].

There is a possibility that smoking cessation might modify psychiatric symptoms (see table 6, page 5) such that it interferes with the diagnosis and treatment of psychiatric disorders (8). Cessation can also dramatically alter blood levels of some psychiatric medications (see table 5, page 5) (8) [II].

II. DISEASE DEFINITION, EPIDEMIOLOGY, AND NATURAL HISTORY

A. DSM-IV NICOTINE USE DISORDERS

DSM-IV includes nicotine dependence and nicotine withdrawal as disorders. Nicotine abuse is not included because clinically significant psychosocial problems from tobacco use are rare (9). Nicotine intoxication is also not included as it is very rare.

B. SPECIFIC FEATURES OF DIAGNOSIS

1. Nicotine dependence

Examples of how the generic DSM-IV criteria for substance dependence apply to nicotine dependence are illustrated in table 2. The applicability and reliability of the DSM diagnosis of nicotine dependence appears high [10]; however, its validity has not been well tested.

Another widely used measure of nicotine dependence is the Fagerstrom Tolerance Questionnaire or the more recent version—the Fagerstrom Test for Nicotine Dependence (table 3) (11, 12). Scores of greater than seven on these scales indicate nicotine dependence.

The severity of nicotine dependence can be illustrated by the fact that only 33% of self-quitters remain abstinent for 2 days and fewer than 5% are ultimately successful on a given quit attempt (13, 14). The strength of nicotine dependence via cigarette smoking is due to several factors: a) nicotine produces a multiplicity of positive reinforcing effects (e.g., improved concentration and mood, decreased anger and weight), b) a bolus of nicotine reaches the brain within 10 seconds after inhalation, producing an almost instantaneous effect, c) nicotine dose can be precisely controlled by the way a cigarette is smoked, d) smoking occurs frequently (e.g., a pack-a-day smoker self-administers nicotine about 200 times a day), and e) there are many cues for smoking (15).

Nicotine dependence and withdrawal can develop with all forms of tobacco use (i.e., cigarettes, chewing tobacco, snuff, pipes, and cigars) and can be maintained with nicotine replacement (i.e., nicotine gum, patch, and nasal spray) (16, 17). The ability of these products to induce or maintain dependence and withdrawal increases with the rapidity of absorption of nicotine, nicotine dose, and availability of the product (15).

Smoking has been labeled the most important preventable cause of death and disease (18, 19). Smoking is responsible for 20% of all deaths in the U.S., and 45% of smokers will die of a tobacco-induced disorder (20). Cigarette smoking causes lung, oral, and other cancers, cardiovascular disease, chronic obstructive pulmonary disease, peptic ulcers, gastrointestinal disorders, maternal/fetal complications, and other disorders (20, 21). Secondhand smoke causes the deaths of thousands of nonsmokers and morbidity in children and other relatives of smokers (22, 23). Smokeless tobacco, pipes, and cigars also cause oral cancers and other problems (20). Although nicotine itself might cause health problems, most of the tobacco-induced disorders appear to be due to the carcinogens and carbon mon-

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TABLE 2. DSM-IV Diagnostic Criteria for Substance Dependence and Examples of Their Application to Nicotine Dependence (10)

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month period:

Criteria	Examples
Tolerance, as defined by either	
A need for markedly increased amounts of the substance to achieve intoxication or desired effect	Most smokers escalate use to 1 pack/day or more by age 25
Markedly diminished effect with continued use of the same amount of the substance	Absence of nausea, dizziness, etc.
Withdrawal, as manifested by either	
The characteristic withdrawal syndrome for the substance	See table 4
The substance is taken to relieve or avoid withdrawal symptoms	Many smokers light up immediately after being in a smoke-free area
The substance is often taken in larger amounts or over a longer period than was intended	Most smokers do not intend to smoke 5 years later, but in fact, over 70% continue to use
There is persistent desire or unsuccessful effort to cut down substance use	77% of smokers have tried to stop, 55% of these have not been able to stop despite repeated attempts and only 5%–10% of self-quitters are successful
A great deal of time is spent in activities necessary to obtain the substance, use the substance or recover from its effects	Leaving worksite to smoke
Important social, occupational or recreational activities are given up or reduced because of substance use	Not taking a job due to on-job smoking restrictions
The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance	Many smokers have heart disease, chronic obstructive pulmonary disease or ulcers and continue to smoke

TABLE 3. Items and Scoring for Fagerstrom Test for Nicotine Dependence (11)

Questions	Answers	Points
1. How soon after you wake up do you smoke your first cigarette?	Within 5 minutes	3
	6–30 minutes	2
	31–60 minutes	1
	After 60 minutes	0
2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?	Yes	1
	No	0
3. Which cigarette would you hate most to give up?	The first one in the morning	1
	All others	0
4. How many cigarettes/day do you smoke?	10 or less	0
	11–20	1
	21–30	2
	31 or more	3
5. Do you smoke more frequently during the first hours of waking than during the rest of the day?	Yes	1
	No	2
6. Do you smoke if you are so ill that you are in bed most of the day?	Yes	1
	No	0

oxide in tobacco smoke rather than nicotine itself (24, 25). Smoking cessation dramatically reduces the risk of heart disease and cancer and prevents continuation of the decline in lung function in those with chronic obstructive lung disease (18).

2. Nicotine withdrawal

The DSM-IV criteria for nicotine withdrawal are listed in table 4. In addition to these symptoms, craving for tobacco, a desire for sweets, increased coughing, and impaired performance on vigilance tasks may occur (16, 17). Withdrawal symptoms begin within a few hours and peak 24–48 hours after cessation (17). Most symptoms last an average of 4 weeks, but hunger and craving can last 6 months or more (17). Nicotine withdrawal symptoms are due, in large part, to nicotine deprivation (16, 17). Cessation of smoking can cause slowing on EEG, decreases in cortisol and catecholamine levels, sleep EEG changes, and a decline in metabolic rate (16). The mean heart rate decline is about 8 beats per minute, and the mean weight gain is 2–3 kg (16). Withdrawal is usually most severe from cigarette abstinence compared to other forms of tobacco and nicotine medications (16, 17). As with all withdrawal syndromes, the severity varies among patients (16).

Cessation of smoking can produce clinically significant changes in the blood levels of several psychiatric medications (table 5) (8). For example, smoking decreases clozapine and haloperidol levels by 30% (8). This effect appears to be due, not to nicotine, but rather to the effects of benzopyrenes and related compounds on the P450 system.

Withdrawal symptoms can also mimic, disguise, or aggravate the symptoms of other psychiatric disorders or side effects of medications (table 6) (8). For example, when an alcoholic smoker who is also nicotine dependent is admitted to a smoke-free ward for alcohol detoxi-

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fication, his or her anxiety, depression, difficulty concentrating, insomnia, irritability, and restlessness could be due to or aggravated by nicotine withdrawal. Also, although uncommon, cessation appears to be able to precipitate a relapse of major depression, bipolar disorder, and alcohol/drug problems (2, 26).

EPIDEMIOLOGY AND NATURAL HISTORY

At present, approximately 50% of the U.S. adult population have never smoked, 25% are current smokers (48 million), and 25% are ex-smokers (11). Among current smokers, most are cigarette smokers, with fewer than 5% using cigars, pipes, or smokeless tobacco (11). The mean number of cigarettes smoked per day is about 20. Between 8% and 15% of smokers are occasional or light smokers (<5 cigarettes/day) (11). The prevalence of smoking has declined dramatically in the U.S.; however, this decline has not been uniform and has abated recently (27). The prevalence of smoking has declined less in those who are younger, female, non-Caucasian, less educated, or poor and those with psychiatric or alcohol/drug problems (27).

The median age of initiation of smoking is 15 (5). Psychiatric predictors of initiation of smoking include use and abuse of alcohol and other drugs, attention deficit disorders, and depressive symptoms; however, smoking precedes the normal age at onset for most psychiatric disorders (2). Twin studies have found that the heritability of smoking is as great as, if not greater than, that for alcoholism (28, 29). Some of the heritability of smoking is shared with and some is independent of that for alcoholism (30).

Within a few years of daily smoking, most smokers begin to develop dependence (5). For example, 50% of smokers in their twenties meet DSM criteria for dependence (31). Also, within a few years of daily smoking, smokers note withdrawal symptoms upon cessation (5). Among older adult daily smokers, 87% (40 million) are estimated to meet DSM-IV criteria for nicotine dependence (32).

About one-third of adults who smoke make a serious attempt to stop smoking each year (27). Over 90% of these attempts to quit are made without formal treatment (27). With self-quitting, 33% of smokers are abstinent for 2 days and 3%–5% are abstinent for 1 year, after which little relapse occurs (13, 14). Most smokers make several quit attempts, so that 50% of smokers eventually quit (27). Smokers with a past or present history of anxiety, depression, or schizophrenia are less likely to stop smoking (2, 8, 33, 34). This could be due to several factors, including increased nicotine withdrawal or nicotine dependence, less social support, or fewer coping skills (2). Smokers who have current alcohol abuse/dependence problems are unlikely to stop smoking unless their alcohol problem resolves (34). Whether alcohol/drug abusers in recovery are less likely to stop smoking is unclear (34).

About 50% of adults who attempt to stop smoking will meet DSM-IV criteria for nicotine withdrawal (17). Smokers who have withdrawal-induced depression or severe craving are less likely to successfully stop smoking (2, 17). In addition, fear of weight gain appears to be a major deterrent to cessation attempts, especially among women (35). The presence of cues for smoking is thought to be crucial in producing withdrawal; thus, withdrawal during inpatient stays on smoke-free units is often not as severe as expected (16).

TABLE 4. DSM-IV Diagnostic Criteria for Nicotine Withdrawal

A. Daily use of nicotine for at least several weeks
B. Abrupt cessation of nicotine use, or reduction in the amount of nicotine used, followed within 24 hours by four (or more) of the following signs:
   1. dysphoric or depressed mood
   2. insomnia
   3. irritability, frustration or anger
   4. anxiety
   5. difficulty concentrating
   6. restlessness
   7. decreased heart rate
   8. increased appetite or weight gain
C. The symptoms in Criterion B cause clinically significant distress or impairment in social, occupational, or other important areas of functioning
D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder

TABLE 5. Effect of Abstinence From Smoking on Blood Levels of Psychiatric Medications (8)

Abstinence Increases Blood Levels		
Clomipramine	Doxepin	Oxazepam
Clozapine	Fluphenazine	Nortriptyline
Desipramine	Haloperidol	Propranolol
Desmethyldiazepam	Imipramine	
Abstinence Does Not Increase Blood Levels		
Amitriptyline	Ethanol	Midazolam
Chlordiazepoxide	Lorazepam	Triazolam
Effect of Abstinence on Blood Levels Is Unclear		
Alprazolam	Chlorpromazine	Diazepam

TABLE 6. Some Examples of Nicotine Withdrawal Symptoms That Can Be Confused With Other Psychiatric Conditions (8)

Anxiety
Depression
Increased REM sleep
Insomnia
Irritability
Restlessness
Weight gain

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III. TREATMENT PRINCIPLES AND ALTERNATIVES

A. INTRODUCTION

There are many similarities between nicotine and other drug dependencies (36, 37). There are also significant differences. For example, although nicotine dependence produces dramatic health problems, it usually does not produce significant interpersonal, financial, legal, or psychological problems. Thus, the present guidelines will in some respects be similar to and in others different than the *American Psychiatric Association Practice Guideline for the Treatment of Patients with Substance Use Disorders: Alcohol, Cocaine, Opioids* (38).

The following sections contain data regarding the likely impact of a variety of treatments for patients who smoke. It is important to note that the bulk of these data are derived from studies of patient groups who are not under psychiatric care. (Exceptions to this are noted.) Expert judgment has been used to determine the applicability of these data to the populations under consideration in this guideline.

B. GOALS OF TREATMENT

Long-term abstinence is the ultimate goal of the treatment of nicotine dependence. Initial goals include moving smokers from not contemplating smoking cessation, to contemplating cessation, to initiating a quit attempt, to quitting for a short period [II] (39). Whether harm reduction (e.g., switching to low nicotine cigarettes or cutting down on the number of cigarettes smoked) is an acceptable goal is debatable because the health benefits from these actions are not well demonstrated, compensatory behaviors occur, and patients may consider harm reduction as a "safe haven," which will undermine later cessation attempts (40). Whether long-term use of nicotine medication is necessary in some smokers is also debatable (41). Management of withdrawal is an important goal in and of itself, especially for those on smoke-free wards (8). Nicotine intoxication is rare; its treatment is not covered here, and the reader is referred to other sources (42).

C. ASSESSMENT

The patient's current smoking status (e.g., current smoker, ex-smoker, never smoked, number of cigarettes/day) needs to be routinely determined. The comprehensiveness of subsequent assessment is determined by the goals and characteristics of potential interventions; i.e., different assessments are necessary to guide the application of brief advice, the intensive treatment of prior treatment failures, or the relief of nicotine withdrawal in an inpatient setting.

1. Readiness to change and motivation to quit

About 40% of current smokers are not considering stopping smoking in the foreseeable future (43). These patients may be uninformed, demoralized about their ability to change, or defensive and resistant to change. Many psychiatric patients are probably in this phase (33, 44). Another 40% of current smokers are ambivalent about quitting (43). These smokers have given serious thought to giving up smoking but are not yet ready to commit to quitting. About 20% of current smokers are intending to quit smoking in the next few months (43). Many of these patients have made a quit attempt in the past year or have taken small steps toward quitting, such as cutting down on the number of cigarettes that they smoke. Making distinctions based on readiness to change is important because, as outlined in section III.D.3., smokers who are not considering quitting appear to need different treatments than those who are ambivalent about stopping or those presently interested in stopping.

2. Diagnosing nicotine dependence

Quantifying a smoker's degree of nicotine dependence is important because highly nicotine-dependent smokers are more likely to need more intensive therapy, especially pharmacotherapy (see section III.F.). Table 2 illustrates the DSM-IV criteria for substance dependence, with examples of how they apply to nicotine dependence (10). Although the DSM system has not been formally tested as a measure to guide therapy, it does appear to be reliable and to have prospective validity (45–47).

The Fagerstrom scale assessments (table 3), widely used in treatment studies, have proven reliability and validity (12, 48). They have been shown to predict success at stopping smoking and, more importantly, to predict which smokers especially benefit from nicotine gum or nasal spray (see section III.F.2.e.).

Several other markers of nicotine dependence have been proposed; e.g., number of cigarettes/day, time to first cigarette (an item on the Fagerstrom scale), cotinine levels, amount of withdrawal on last attempt, and number of unsuccessful quit attempts. However, with the possible exception of time to first cigarette (48), these have yet to be shown to have significant treatment utility.

In summary, both the DSM-IV and Fagerstrom scale assessments are recommended [II].

3. Motivators for and barriers to quitting

The most common reasons for trying to stop smoking are to improve health and in response to social pressure (49). The most common barriers are fear of weight

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TABLE 7. Strategies of Psychiatric Management for Patients Who Smoke

- Assess smoking behavior, motivation to quit, motivators for and barriers to quitting
- Establish a therapeutic alliance
- Advise patient to stop
- Assist in cessation
- Arrange follow-up

TABLE 8. Recommended Treatments for Nicotine Dependence

Psychosocial Therapies	Somatic Therapies
Multicomponent behavior therapy [I]	Nicotine gum [I]
Skills training/relapse prevention [II]	Transdermal nicotine [I]
Stimulus control [II]	Nicotine gum or transdermal nicotine + behavior therapy [I]
Rapid smoking [III]	Nicotine gum + transdermal nicotine [II]
Self-help materials [III]	Clonidine [II]
	Nicotine nasal spray [III]

gain, fear of withdrawal, and fear of failure (49). Assessment of motivators and barriers appears helpful in motivating patients and is recommended [III] (50). Exacerbation of psychiatric symptoms is likely an additional barrier for psychiatric patients (39).

4. Smoking history

Seventy percent of smokers have tried to stop in the past (2, 3); thus, the lessons learned and patient perceptions about these prior attempts need to be assessed [III]. The more important areas to be assessed include the smoker's reasons for quitting, any change in psychiatric functioning when he or she tried to stop, cause of relapse (e.g., whether the relapse was related to withdrawal symptoms or exacerbation of a psychiatric disorder), how long he or she remained abstinent, whether he or she sought treatment before, adequacy of prior treatment in terms of dose and duration, compliance with treatment, whether he or she believed treatment helped, and his or her expectations about future treatment [III].

5. Psychosocial factors

Since social support is a major predictor of cessation (5, 11), the smoking status (e.g., never smoked, ex-smoker, current smoker) of others in the household and close friends should be assessed [III]. If others in the household are current smokers, their willingness to quit at the same time as the patient or not to smoke in front of the patient should be determined. Whether and how others in the household and friends have supported or undermined prior quit attempts should be assessed.

6. Patient preferences

Smokers vary in their treatment preferences. Many patients have strong likes or dislikes about pharmacotherapy, group therapy, and individual therapy. Patients sometimes prefer to stop smoking on a certain date. These preferences and their basis should be elicited and should be considered when developing a treatment plan [III].

7. Nicotine/cotinine and carbon monoxide levels

Nicotine and cotinine levels can be measured in blood, saliva, and urine (52). Nicotine level can reflect smoking over the last few hours; whereas the level of cotinine, a metabolite of nicotine, is sensitive to smoking in the last 7 days and offers a better measure of total daily nicotine exposure (52). Measurement of cotinine level has been proposed to help guide nicotine replacement, but the utility of this strategy has not been well tested (53). Carbon monoxide level is usually measured by breath and reflects smoking only over the last few hours (52). The major asset of carbon monoxide level is that it is easily measured and can be used to verify cessation when patients are using nicotine replacement (52). Carbon monoxide measurement can be used to motivate cessation or reinforce abstinence, but its efficacy is unclear (54).

Patients usually are truthful about their smoking status and the number of cigarettes smoked per day (55). Thus, although the described measures show promise as helpful assessments, at present they are not necessary for evaluation of smoking cessation.

8. Overall psychiatric/general medical evaluation

Psychiatric assessment in smokers places special emphasis on screening for affective and substance use disorders because these disorders are prevalent among smokers and have been shown to interfere with smoking cessation [I] (2, 34). Smokers should also be briefly screened for the signs and symptoms of most common causes of morbidity and mortality among smokers; i.e., cardiovascular disease, lung cancer, and chronic obstructive pulmonary disease (20, 21). Among smokeless tobacco, cigar, and pipe users, mouth and upper airway cancers are the most common causes of tobacco-induced morrality, and patients should be screened for their presence (20, 21).

D. PSYCHIATRIC MANAGEMENT

In this guideline, psychiatric management refers to the skills and techniques that are critical to the care of all patients with nicotine dependence (table 7), regardless of what specific techniques are used (table 8). These techniques are common to all smoking interventions and should be used with all smokers. Meta-analyses have found such techniques to increase quit rates by a factor of 1.5 to 2.0 (3, 56–58). In addition to the present guideline, several other descriptive reviews of the skills and techniques critical to smoking interventions have been published (59–67).

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1. Establishing a therapeutic alliance

Nicotine dependence is a chronic relapsing disorder; e.g., most smokers require 5–7 attempts before they finally quit for good (27). Many patients don't realize it usually takes several attempts to stop smoking, and they will need to be remotivated to attempt to quit after a failure [II] (61). Because of this, it is important to establish a therapeutic relationship such that the patient will return to the psychiatrist for subsequent quit attempts, if necessary (61).

Advice is best given in a nonjudgmental, empathic, supportive manner [III] (39, 61). No studies have been conducted to test whether confrontational styles of interventions used in treating other drug dependencies are useful with smoking. In patients with a present or past psychiatric disorder, it is important to convey the message that simply having a psychiatric disorder is not a reason not to make a quit attempt [II] (63, 68).

2. The treatment setting

Treatment best occurs in a system that encourages cessation (61). The psychiatrist should consider making his or her worksite smoke-free (61, 69). Achieving this on psychiatric inpatient units may be especially important, as discussed later in section IV.C.3.a.

3. Initial interventions

a. Increasing motivation and readiness to change. Smokers who are not ready to stop or are ambivalent about stopping smoking are given motivational interventions such as personalized information and feedback on the risks of smoking that are particular to the individual patient [III] (39). If feelings of demoralization are uncovered, they can be addressed by informing the patient that even the most committed smokers make several quit attempts before they are finally successful [III]. Revisiting smoking cessation at periodic intervals, especially when smoking-related illnesses (e.g., bronchitis) or other special situations (e.g., pregnancy, child with asthma) occur, can sometimes motivate smokers to consider quitting [II]. Documenting smoking status in the medical record may help to facilitate such follow-up.

Smokers may express negative feelings or fears about quitting. Problem solving around these fears appears helpful [III]. Clarification and legitimation of their feelings and expressions of support and respect also may be helpful [III]. It is useful to explore the smoker's reasons for smoking as well [III]. Smokers who become chronically ambivalent may benefit from encouragement to take small steps toward action, such as reducing the number of cigarettes they smoke or trying to quit for just 24 hours [III]. The psychiatrist supports self-efficacy by identifying and praising past behavioral change and encouraging the use of strategies effective in the past. Finally, and most importantly, no matter what the smoker's level of motivation, direct advice to stop smoking should be given [I].

Strategies such as those mentioned have been formalized in the stages of change and motivational enhancement models. There are only a few studies verifying the efficacy of providing advice for smoking cessation based on stages of change (70). Although motivational enhancement therapy appears to be effective for alcohol dependence, its effectiveness with nicotine dependence has not been tested. On the other hand, clinical experience indicates that these approaches may be useful [III].

b. Initial intervention for patients who wish to stop. The most widely used initial interventions are the National Cancer Institute's 4 As strategies based on smokers seen in general medical settings. The program consists of four steps, or four As (61):

- *Ask* and record smoking status (covered in section III.C.).
- *Advise* to stop: Clear direct advice to stop smoking is essential. It is best to elicit a personal reason to stop smoking from the patient. One of the best ways to elicit such reasons is to ask if the patient has thought about stopping before and why he or she was interested in stopping on the most recent occasion.
- *Assist* the patient in addressing cessation: The psychiatrist should elicit a commitment to quit. If a specific quit date is agreed upon, the psychiatrist should offer treatments at that time or immediately before the quit date. If the patient is not ready to make a commitment to a quit date, the psychiatrist should plan to readdress smoking at a later date, encourage the patient to reconsider, and offer to help if the patient changes his or her mind. In addition, the psychiatrist should give written materials focused on either motivating the patient to make a quit attempt or suggesting tips on how to make the cessation attempt successful.
- *Arrange* follow-up: If the patient is attempting smoking cessation, the psychiatrist or the psychiatrist's staff should call or see the patient 1–3 days after the quit date. Waiting 7–10 days after the quit date is usually too long, as many patients relapse in the first few days after the quit date (13).

Brief advice by the physician based on protocols similar to the National Cancer Institute approach typically doubles quit rates from approximately 5% to 10% [I] (3, 56–58, 71, 72). Advice from nonphysicians is also effective (3, 58), and advice from multiple sources is more effective (3, 58). Although not tested, brief advice is probably less successful in those psychiatric patients who have poor self-esteem and a more chaotic social, environmental, and psychologic status. Nevertheless, such brief advice from the psychiatrist and other psychiatric personnel (e.g., nurses, social workers) is a recommended treatment because it is a base therapy upon which other therapies can be added as needed [I].

4. Educating about nicotine dependence and its treatment

Many smokers don't realize their smoking may be a form of nicotine dependence (11). Key points to convey to patients include: a) the large majority of smokers try multiple times before they finally quit, but with persist-

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ence half of all smokers quit; b) the nature (see table 4) and duration (4 weeks or longer) of true withdrawal symptoms; c) nicotine withdrawal can be relieved with nicotine replacement; and d) most smokers fail early on, but if the smoker is able to remain abstinent for 3 months, relapse is unlikely [III] (61).

5. Timing of cessation attempt

The timing of the cessation attempt is based on the patient's readiness to change (see section III.D.3.b.) and the psychiatrist's evaluation of whether the patient's psychiatric status is sufficiently stable [III] (68). Thus, cessation of smoking would likely not be recommended when the patient is exhibiting psychiatric symptoms but could be recommended when symptoms have abated and maintenance psychotherapy or pharmacotherapy is underway [II] (68).

Since smoking cessation can induce withdrawal symptoms that could interfere with psychiatric diagnosis and treatment and since cessation can change the blood levels of several psychiatric medications (tables 4 and 5) (8), it may be best to recommend cessation when no major changes in the treatment of a psychiatric disorder are underway [III] (68). If cessation has to be delayed, the psychiatrist should be sure to keep cessation on the treatment goal list to address at a later time [I].

On the other hand, sometimes smoking cessation may be integrated into the lifestyle changes that are a part of certain psychiatric treatment (e.g., during cessation of alcohol use) (see section V.A.1.). Also, admission to a smoke-free inpatient unit can be used to motivate a cessation attempt. Finally, intervention is indicated if the patient has recently been diagnosed with a smoking-related illness, as smokers with such illnesses generally have higher success rates (49, 73) (see section V.B.1.).

6. Abrupt versus gradual cessation

Most patients use and most clinicians recommend abrupt cessation of smoking rather than gradual reduction (74). Gradual reduction has been thought to be less successful because patients appear to have difficulty achieving further reductions once smoking 5–10 cigarettes per day (53). On the other hand, most of the scientific data available suggest no difference in the outcomes of abrupt versus gradual cessation (3, 53, 56, 75); thus, patient preferences to use gradual reduction should be respected [III]. However, with a gradual approach, patients should be advised to set a date by which they will completely stop [III] and not to use nicotine replacement therapy until they have stopped using cigarettes [II].

7. Dealing with weight gain concerns

One of the most common fears around smoking cessation is weight gain (76). On average, smokers weigh 2–3 kg less than persons who have never smoked and when they stop smoking they gain weight until they are similar in weight to those who have never smoked (35). The large majority of smokers gain weight over the first few months postcessation, but many later lose much or all of this weight. Women who are already trying to keep weight off gain the most (77).

Even though the health benefits of stopping smoking clearly outweigh the health risks of weight gain (35), fear of weight gain is a major deterrent to smoking cessation, especially among women (77). However, weight gain after stopping smoking does not cause relapse to smoking (17). In fact, concentrated efforts to control weight gain by dieting during abstinence increase, not decrease, relapse back to smoking (78, 79). This may be because trying to stop smoking and trying to diet at the same time is just too difficult. Rather than dieting, increasing physical activity upon cessation, learning healthy eating strategies, or convincing the smoker to tolerate a moderate amount of weight gain over the first 3 months and to work on losing weight later on can be recommended [III] (80). Nicotine gum, but not the nicotine patch, appears to delay weight gain and could be used to delay attempts to control weight until relapse to smoking is less likely [III] (81)

8. Advising about alcohol and caffeine use

Alcohol use is a risk factor in most studies of smoking relapse (82); thus, either diminishing alcohol intake or abstaining from alcohol is recommended [III]. Caffeine use typically does not change with cessation (17), and whether caffeine use is a risk factor for relapse is unclear (83). Smoking increases the metabolism of caffeine, and smoking cessation increases caffeine levels by 50%–60% (84). Since many of the symptoms of caffeine intoxication and nicotine withdrawal overlap (e.g., anxiety, insomnia, restlessness), reducing caffeine intake postcessation might be helpful; however, the one study to test this hypothesis was negative (84). In addition, abruptly stopping caffeine could induce a withdrawal syndrome of its own (85). In summary, with this contradictory evidence, patient preferences on whether to change caffeine intake should be respected [III].

9. Follow-up visits

The first follow-up should occur within 1–3 days after the quit date, as the majority of smokers relapse in the first few days [I] (13). The scheduling of further follow-ups should be determined by the patient's perceived need, past history of cessation, past psychiatric history, whether he or she is taking a medication whose blood level might increase with cessation (table 5), and whether he or she is taking antismoking medications that require visits to monitor side effects or plan tapering [III].

At follow-up, the psychiatrist assesses whether the patient has smoked and, if so, the number of cigarettes smoked per day [II] (61). The psychiatrist also assesses the severity of withdrawal symptoms, the onset of any

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psychiatric symptoms or alcohol/drug use, how the patient dealt with high-urge situations, any medication side effects, etc., and tailors the treatment accordingly [II] (61). Most, but not all, studies suggest that brief follow-ups (including telephone calls) increase quit rates [II] (57, 58).

10. Dealing with slips and relapses

Since smoking even one cigarette during a cessation attempt very often portends a full-blown relapse (86), reports of slips should prompt immediate planning around either changes in behavior therapy (e.g., discuss ways to avoid or cope with situation that led to slip) or pharmacotherapy (e.g., increase dose, change medications) [III]. If the patient has fully relapsed, the psychiatrist should praise the patient for even limited success [III]. The patient and the psychiatrist should then discuss what was learned with this quit attempt and when the patient would like to think about trying again [III]. Most patients who relapse continue to be interested in stopping smoking; thus, the psychiatrist should discuss setting a time to reconsider another cessation attempt [III].

E. SPECIFIC PSYCHOSOCIAL TREATMENTS

1. *Behavior therapies*

a. Introduction. Behavioral therapy is based on the theory that learning processes operate in the development, maintenance, and cessation of smoking. Many of the recommendations described under psychiatric management (see section IV.A.3) are actually based on the principles of behavioral therapy. The following sections briefly describe formal behavioral techniques for cessation. For more information, the reader is referred to several recent descriptive (51, 62, 65, 67, 71, 72, 74, 87–91) and meta-analytic (3, 57) reviews of behavior therapy.

b. Goals. Major goals of behavior therapy are to change the antecedents (including cognitions) to smoking, to reinforce nonsmoking, and to teach skills to avoid smoking in high-risk situations.

c. Efficacy. There are over 100 controlled prospective studies verifying the efficacy of behavior therapy (57, 71, 72, 92). Typically, behavioral therapies are a multimodal package of several of the specific treatments described later in this guideline. In most reviews/meta-analyses, 6-month quit rates with behavior therapy packages are 20%–25%, and behavior therapy typically increases quit rates twofold over control groups (3, 56, 57, 71, 72, 90, 92). Given this large database of efficacy, multimodal behavior therapy is a recommended first-line therapy [I].

d. Specific techniques. Although multimodal behavior therapies have been validated, much less research is available on the efficacy of the individual techniques in the behavioral therapy package. The following sections review each technique and indicate those that are recommended treatments.

1) Skills training/relapse prevention. Skills training, relapse prevention, and their variants (problem solving, coping skills, and training in stress management) have patients anticipate a large number of situations or processes that are likely to lead to urges to smoke or to prompt a slip (e.g., a party, an argument, a thought). Early on in cessation, it is often best to avoid high-risk situations (91). Later, patients plan strategies to cope with these situations. Behavioral coping includes removing oneself from the situation, substituting other behaviors (e.g., exercising, taking a walk), or utilizing skills to manage the triggers (e.g., refusal skills, assertiveness, time management). Cognitive coping includes identifying maladaptive thoughts, challenging them, and substituting more effective thought patterns (e.g., reminding oneself of why it is important to stop smoking or that the urge will pass). Another target is to prevent the abstinence violation effect that transforms a slip to a relapse (e.g., not viewing a slip as a catastrophe).

The results of individual trials specifically testing relapse prevention have been mixed (91, 93). However, two recent meta-analyses concluded problem solving/skills training/relapse prevention significantly increases cessation rates (3, 56); thus, skills training/relapse prevention is a recommended component treatment [II].

2) Stimulus control. Stimulus control usually includes self-monitoring prior to a quit attempt to facilitate identification of stimuli associated with smoking (74). Stimulus control also includes initially removing or avoiding cues associated with smoking to reduce urges to smoke. Patients are encouraged to discard all cigarettes, remove lighters, ashtrays, and matches, and avoid other smokers and situations associated with smoking.

Studies of whether stimulus control is effective on its own have produced mixed results (3). However, stimulus control appears to be a very helpful procedure in multicomponent treatment in that it serves as the base for many behavioral techniques (e.g., relapse prevention); thus, stimulus control is a recommended treatment component of behavior therapy [II].

3) Aversive therapy. The rationale of aversive therapy is to make smoking more aversive and less reinforcing by inducing mild nicotine intoxication symptoms of nausea, dizziness, etc., when the patient smokes. The original version of this type of treatment was rapid smoking, in which patients inhale cigarette smoke every few seconds (71, 72). Many well-controlled studies of rapid smoking have been conducted, and most reviews and meta-analyses have concluded rapid smoking is efficacious (3, 51, 56, 71, 72, 74, 92). Compliance with rapid smoking, as with all aversive therapies, is difficult, and a strong therapeutic alliance or a priori contracts may be used to improve compliance [III]. Other, less-aversive versions of therapy include focused smoking, in which smokers smoke at a regulated rate, and smoke holding and rapid puffing, in which patients smoke rapidly but do not inhale. Whether these less-aversive tech-

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niques are as effective as rapid smoking is debatable (51, 71, 72, 74, 92).

Although most therapists no longer use rapid smoking because of health and compliance concerns, rapid smoking appears to be safe in healthy patients (51, 71, 72, 74) and those with medical disorders may be able to participate with medical supervision [II]. In summary, rapid smoking is a recommended component of behavior therapy for those smokers willing to comply [II].

4) Social support. Although many studies indicate social support for stopping smoking is a predictor of cessation, attempts to harness social support as an intervention have been mostly unsuccessful (51, 72, 74). Buddy systems, increasing cohesion in group therapy, and teaching spouses to reinforce not smoking have not consistently increased quit rates (3, 51, 72, 74). The lack of success of such interventions is likely related to their failure to influence the level of support. A recent study that was successful in enhancing levels of social support did enhance smoking cessation outcome (94). Most clinicians and programs address social support because lack of social support appears to undermine cessation attempts (95). In summary, social support lacks sufficient evidence to be recommended but is a promising treatment.

5) Contingency management. In this procedure, smokers are either reinforced for not smoking with the presentation of some reward or punished for smoking by the loss of some reward. For example, patients place a deposit that is either refunded contingent on not smoking or forfeited for smoking, using carbon monoxide level as an objective measure of smoking. Contingency contracting is effective while the contingency is in place, but whether this effect persists after the contingency is removed is unclear (51, 72, 74). Thus far, procedures to wean smokers from such contingency procedures have not been developed. Meta-analysis of long-term studies does not support the efficacy of contingency contracting with smoking (3). In summary, contingency contracting lacks sufficient evidence to be recommended.

6) Cue exposure. Cue exposure involves repeatedly exposing patients to real or imagined situations that evoke potent urges to smoke in an attempt to extinguish the ability of these situations to evoke urges to smoke. Four randomized, controlled trials of cue exposure have been published (96–99), and meta-analysis does not support the efficacy of cue exposure (3). In summary, cue exposure lacks sufficient evidence to be recommended.

7) Nicotine fading. In this procedure, patients gradually reduce the nicotine yield of their cigarette. This technique should not be confused with reducing the number of cigarettes per day, which was covered in section III.D.6. With nicotine fading, some smokers increase the number of cigarettes or smoke each cigarette more intensely, but overall nicotine consumption is significantly reduced (51, 71, 72, 74, 90). The evidence that this treatment increases quit rates is mixed (51, 71, 72, 90), and meta-analyses do not support its efficacy (3, 56). In summary, nicotine fading lacks sufficient evidence to be recommended.

8) Relaxation. Relaxation is often taught to manage relapse situations associated with anxiety. Although often used in multicomponent programs, relaxation itself usually has not been shown to increase smoking cessation (51, 71, 72, 74, 90), and meta-analysis does not support its efficacy (3). In summary, relaxation lacks sufficient evidence to be recommended.

9) Physiological feedback. The rationale for this procedure is that giving patients immediate and concrete positive feedback of the benefits of not smoking by showing them that their carbon monoxide level declines with cessation will reinforce not smoking. Controlled trials of the efficacy of such feedback have produced mixed results (55, 56), and the one meta-analysis did not support its efficacy (3). Thus, physiological feedback lacks sufficient evidence to be recommended.

e. Implementation. Both group and individual formats have been used for behavioral therapies for smoking cessation (57, 58, 74). Groups are often used to increase social support for stopping smoking, and individual therapy is used to tailor treatment to the specific problems of the individual smoker. Meta-analyses suggest little difference in outcomes across group versus individual therapy (3, 57, 58). Thus, patient preferences and availability of specific treatments should be considered when recommending group versus individual therapy [III].

Since two-thirds of patients relapse in the first week (13, 86), most treatment is optimally timed before or very soon after cessation [I]. In most cessation programs, several sessions occur over the few weeks immediately prior to and immediately after the quit date (74).

The most common providers of behavior therapy are voluntary organizations (e.g., the American Lung Association), wellness programs, or health educators/psychologists in health care organizations (100). A major problem is that, although clearly effective, behavior therapy is often not available to patients or available only intermittently, is costly, and is not integrated into the health care system (60, 100, 101). As a result, many of those motivated to quit forego behavior therapy (60, 101).

Although recent studies of matching particular behavior therapies to particular types of smokers have been published (102, 103), at present there are insufficient data to recommend specific matching strategies. Psychiatric patients, including those with substance abuse/dependence, are more likely to benefit from behavior therapy because of their high incidence of psychosocial problems, poor coping skills and, often, past history of benefit from such therapy (68).

2. Self-help materials

The major goals of self-help materials are to increase motivation and impart cessation skills. Written manuals are the most common form of self-help material, although recently computer and video versions have been

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developed (87, 104). Most self-help materials are behaviorally oriented. Whether self-help interventions used without additional contact or support increase smoking cessation is debatable (14, 57, 71, 72, 74, 87, 92). Reactive telephone counseling via a hot-line appears to increase cessation when added to other self-help interventions (104–106), and meta-analyses suggest a small positive effect (3, 57). Self-help materials appear to be more effective in patients who are less nicotine-dependent (107, 108) and more motivated (87). Use of multiple modes of therapy (e.g., written materials plus phone contact) appears to enhance the effectiveness of self-help (58, 87, 104). Tailoring materials to the specific needs and concerns of each patient also appears helpful (70, 108). In summary, self-help materials are recommended as part of a behavioral therapy package [II].

3. Educational and supportive groups

The goals of educational and supportive groups are to teach patients the harms of smoking and benefits of cessation and to provide group reinforcement for not smoking. The efficacy of education and group support in themselves (i.e., without the behavioral techniques listed above) is debatable (3, 71, 72, 109). On the other hand, the clinical experience of the Work Group on Nicotine Dependence and other clinicians is that group support is important for some patients; thus, educational and supportive groups are considered a promising therapy [III].

4. Hypnosis

The usual goal of hypnotherapy for smoking cessation is to implant nonconscious suggestions that will deter smoking; e.g., smoking will be unpleasant. Three meta-analyses reported hypnosis was efficacious (56, 57, 92); however, the most recent meta-analysis did not (3). In addition, several quantitative reviews concluded the efficacy of hypnosis was unproven (51, 62, 74). Much of this discordance is because most hypnosis trials have poor methodologies and were excluded from consideration in some meta-analyses or reviews. Given the conflicting evidence, hypnosis is rated as a promising treatment [III].

5. Other therapies

The goal of 12-step programs for smoking cessation (as modified from Alcoholics Anonymous) is to have the smoker accept that he or she is powerless over smoking and work through 12 goals (or steps) that help break down denial. Several organizations have outlined how to apply the 12-step model to smoking, and a national self-help organization— Nicotine Anonymous— exists (110). However, there are no scientific tests of 12-step programs for smoking cessation.

Exercise might be helpful as it is thought to increase self-esteem, relieve stress, emphasize the new role of an abstinent smoker as a healthy person, and help manage weight gain. Controlled evaluations of exercise for smoking cessation have produced mixed results, but more recent studies have been positive (111, 112). The major difficulty has been poor compliance with high-intensity exercise regimens. Although recent research indicates psychological benefit occurs with low-intensity activity, whether increasing low-level activity might be helpful in smoking cessation has not been tested. In summary, exercise/activity is a promising therapy.

Biofeedback, family therapy, interpersonal therapy, and psychodynamic therapy have been used with other drug dependencies (38) and might be applicable to smoking cessation; however, there are either no or only a few descriptions of adapting these to treat smoking. In summary, none of these treatments have sufficient evidence to be recommended. (Acupuncture is covered with somatic therapies in the next section.)

F. SOMATIC TREATMENTS

1. Introduction

Pharmacotherapies can be divided into replacement therapy, antagonist therapy, therapies to make drug intake aversive, and nonnicotine medications that mimic nicotine effects (113, 114). Nonmedication somatic therapies include acupuncture and devices. The following are brief descriptions of these therapies. For more information, the reader is referred to recent descriptive (51, 56, 62, 67, 71, 72, 101, 113–123) and meta-analytic (3, 57, 92, 115, 124–129) reviews.

2. Nicotine Replacement Therapy

a. Goals. The goal of nicotine replacement therapy is to relieve withdrawal, which will allow the patient to focus on habit and conditioning factors when attempting to stop smoking. After the acute withdrawal period, nicotine replacement therapy is gradually reduced so that little withdrawal should occur.

b. Description of products.

1) Nicotine gum. Nicotine ingested through the gastrointestinal tract is extensively metabolized on first pass through the liver (42). Nicotine gum (nicotine polacrilex) avoids this problem via buccal absorption (42). The gum contains 2 or 4 mg of nicotine that can be released from a resin by chewing (113). The original recommendation was to use one piece of 2-mg gum every 15–30 minutes as needed for craving. More recent work suggests scheduled dosing (e.g., 1 piece of 2-mg gum/hour), and 4-mg gum for highly nicotine-dependent smokers is more effective (62, 113). The original recommended duration of treatment was 3 months. Many experts believe longer treatment is more effective; however, the two trials of longer duration produced contradictory results (41).

Nicotine absorption from the gum peaks 30 minutes after beginning to use the gum (42). Venous nico-

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tine levels from 2- and 4-mg gum are about one-third and two-thirds, respectively, of the steady-state (i.e., between cigarettes) levels of nicotine achieved with cigarette smoking (42). Nicotine via cigarettes is absorbed directly into the arterial circulation; thus, arterial levels from smoking are 5–10 times higher than those from the 2- and 4-mg gums (130). Absorption of nicotine in the buccal mucosa is decreased by an acidic environment; thus, patients should not use beverages (e.g., coffee, soda, juice) immediately before, during, or after nicotine gum use (130). Nicotine gum (2- and 4-mg doses) has recently been approved as an over-the-counter medication.

2) Nicotine patch. The four transdermal formulations take advantage of ready absorption of nicotine across the skin (115, 131, 132). Three of the patches are for 24-hour use and one is for 16-hour (waking) use. Starting doses are 21–22 mg/24-hour patch and 15 mg/16-hour patch. Patches are applied daily each morning, beginning upon cessation of smoking. Nicotine via patches is slowly absorbed so that on the first day venous nicotine levels peak 6–10 hours after administration. Thereafter, nicotine levels remain fairly steady with a decline from peak to trough of 25% to 40% with 24-hour patches (131). Nicotine levels obtained with the use of patches are typically half those obtained by smoking (131).

After 4–6 weeks patients are usually tapered to a middle dose (e.g., 14 mg/24 hours or 10 mg/16 hours) and then again in 2–4 weeks to the lowest dose (7 mg/24 hours or 5 mg/16 hours). Most, but not all, studies indicate abrupt cessation of the use of patches often causes no significant withdrawal; thus, tapering may not be necessary (133). The recommended total duration of treatment is usually 6–12 weeks (115, 133). Two nicotine patches are now available over the counter. The treatment schedule for one of these patches is now 6 weeks only with no tapering.

3) Nicotine nasal spray. Nicotine nasal spray is a nicotine solution in a nasal spray bottle similar to those used with antihistamines (133–135). This treatment is likely to be marketed in the United States in 1996. Nasal sprays produce droplets that average about 1 mg per administration. This formulation produces a more rapid rise in nicotine levels than does nicotine gum; the rise in nicotine levels produced by nicotine spray falls between those produced by nicotine gum and cigarettes. Peak nicotine levels occur within 10 minutes, and venous nicotine levels are about two-thirds those of between-cigarette levels (136). Smokers are to use the product ad-lib up to 30 times/day for 12 weeks, including a tapering period.

4) Nicotine inhalers. These are plugs of nicotine placed inside hollow cigarette-like rods. The plugs produce a nicotine vapor when warm air is passed through them (137–139). Absorption from nicotine inhaler is primarily buccal rather than respiratory (140). More recent versions of inhalers produce venous nicotine levels that rise more quickly than with nicotine gum but less quickly than with nicotine nasal spray, with nicotine blood levels of about one-third that of between-cigarette levels (141). The inhaler is to be used ad-lib for about 12 weeks.

5) Other nicotine delivery devices. Nicotine lozenges for buccal absorption are available in some countries, but not in the United States.

6) Lobeline. Lobeline is a nontobacco drug that shares tolerance with nicotine on several measures (142). It has been included in several over-the-counter antismoking medications. The pharmacokinetics of lobeline in humans has not been reported.

c. Efficacy

1) Nicotine withdrawal. Nicotine replacement therapy is often used solely for the purpose of relieving withdrawal symptoms in outpatient or inpatient settings. Many studies have shown nicotine replacement therapy decreases withdrawal symptoms in outpatient settings (16, 17). Anxiety, anger/irritability, depression, difficulty concentrating, and impatience are usually relieved by nicotine replacement; whereas insomnia and weight gain are not consistently decreased (16, 17). This is true for nicotine gum, patch, spray, and inhaler. Nicotine gum appears to be more likely to delay weight gain than nicotine patch (101). Nicotine gum at 2-mg ad-lib appears less likely to reduce craving than nicotine patch or nasal spray; however, this may be a dose-related issue, as the 4-mg dose appears to better reduce craving (143). Whether nicotine gum, patch, nasal spray, or inhaler is better at relieving withdrawal is unknown. Higher doses of nicotine replacement therapy only marginally decrease withdrawal symptoms (101). Whether nicotine inhaler or lobeline decreases withdrawal symptoms is unclear (138, 144).

2) Long-term abstinence with adjunctive psychosocial therapy. Eleven meta-analyses of over 50 studies that included a psychosocial therapy (usually behavior therapy) along with nicotine replacement all conclude that nicotine gum and nicotine patch increase long-term quit rates by a factor of 1.6–2.4 (3, 56–58, 101, 115, 124, 126, 127, 133, 145, 146). The three studies of nicotine nasal spray reported increases in abstinence in the same range (135, 147, 148). The one study of nicotine inhaler found a tripling of the quit rate (138). Lobeline has not been shown to be effective (113, 123, 149). Higher doses of nicotine gum are more effective in more nicotine-dependent patients (115, 127). Whether higher doses of nicotine patch are more efficacious is debatable (53).

3) Long-term abstinence with minimal adjunctive therapy. Often, interventions for smoking cessation consist of brief advice (10 minutes) plus a prescription for nicotine replacement. Although early reviews indicated nicotine gum was not more effective than placebo in this setting, more recent meta-analyses indicate nicotine gum increases quit rates by a factor of around 1.5 (3, 57, 58, 92, 101, 115, 124, 126, 127). In addition, controlled studies have found that nicotine gum doubles quit rates even when given with no adjunctive therapy; i.e., in an over-the-counter setting (FDA Advisory Panel Hearings, Sept. 29, 1995). The nicotine patch is clearly

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effective when given with minimal therapy and doubles quit rates (3, 34, 56, 101, 115, 127, 133, 146). Both the 24- and 16-hour patch double quit rates even in an over-the-counter setting (FDA Advisory Panel Hearing, March 17, 1996). Finally, although nicotine gum and patch are efficacious in these settings, overall quit rates are low (e.g., 10%–20%). Nicotine nasal spray, nicotine inhaler, and lobeline have not been tested in this setting.

4) Patch plus gum. Three controlled trials indicate using nicotine gum (2 mg) ad-lib in addition to a nicotine patch increases quit rates over either therapy used alone (119). Such combined therapy does not appear to significantly increase side effects; thus, this is a recommended treatment [II].

5) Summary of recommendations. Nicotine patches and nicotine gum are recommended initial pharmacotherapies for smoking cessation [I]. Nicotine nasal spray is also recommended but because it has a smaller empirical base and appears to have significant side effects (see section III.F.2.d.3), it is recommended as a treatment for those who have failed to stop smoking using the nicotine patch or gum [II]. Because of a limited database, the nicotine inhaler is classified as a promising treatment. Lobeline lacks sufficient evidence of efficacy to be recommended.

d. Side effects.

1) Nicotine gum. Major side effects from nicotine gum are very rare and side effects rarely deter use (24). Minor side effects are of mechanical origin (e.g., difficulty chewing, sore jaw) or of local pharmacological origin (e.g., burning in mouth, throat irritation). Tolerance develops to most side effects over the first week (24). Education about proper use of the gum (e.g., do not chew too vigorously) decreases side effects (24). Originally, some disorders were listed as contraindications to use of nicotine gum (e.g., cardiovascular disease, pregnancy, hypertension), but given that nicotine blood levels are much lower with nicotine gum than with cigarettes, these contraindications have been dropped (24, 25).

The only psychiatric/psychological side effect of nicotine gum is the continuance of nicotine dependence (15). Abrupt cessation of nicotine gum can produce withdrawal symptoms similar to, but less intensive than, that from cigarettes (15). Gradual reduction in the use of nicotine gum usually produces no or very minor symptoms (15). About 10%–20% of those who stop smoking with the help of nicotine gum continue to use nicotine gum for 9 months or more, but few use the gum longer than 2 years (41). There are several lines of evidence that most long-term use is not dependence. For example, all but 1%–2% of smokers eventually stop gum use, the amount of gum use at long-term follow-up is minimal (usually 12 mg/day), the amount of gum use decreases over time, and weaning off the gum usually requires only education and reassurance even in long-term users (15, 41, 150). Instead, long-term use appears to most often represent the patient's desire to extend the duration of therapy for fear of returning to smoking if nicotine gum use is stopped. Harmful effects of long-term use of nicotine gum have not been studied but are unlikely given the absence of exposure to carcinogens or carbon monoxide and the much lower levels of nicotine from nicotine gum than from cigarettes (24, 25).

2) Nicotine patch. Significant medical problems with nicotine patches have not been found (24, 25, 115, 151). The most common minor side effects are skin reactions (50%), insomnia and increased or vivid dreams (15% with 24-hour patches), and nausea (5%–10%) (24, 115, 151). Tolerance to these side effects usually develops within a week. Rotation of patch sites decreases skin irritation. Although debatable, insomnia reported in the first week postcessation appears to be mostly due to nicotine withdrawal rather than the nicotine patch itself (152). A 24-hour patch can be removed before bedtime to determine if the insomnia is due to the nicotine patch. Insomnia usually abates without treatment after 4–7 days. Although one series of case reports suggested concomitant use of cigarettes and nicotine patches caused myocardial infarction, later analyses and prospective empirical studies in smokers with active heart disease indicated this prior report was incorrect (23). Abrupt cessation of the nicotine patch does not appear to produce significant withdrawal symptoms, and long-term use has not been a problem (151).

3) Nicotine nasal spray. The major side effects from nicotine nasal spray are nasal and throat irritation, rhinitis, sneezing, coughing, and watering eyes (135, 147, 148). One or more of these occur in over three-quarters of the patients. Long-term nasal problems from use of nicotine nasal spray is usually not a problem (147). Whether abrupt cessation of nasal spray produces withdrawal has not been studied. Nicotine nasal spray does appear to have some dependence liability, as indicated by the fact that in some studies, several patients who quit smoking with nicotine nasal spray continued to use it for long periods (147).

4) Nicotine inhaler. No serious medical side effects have been reported with nicotine inhalers (137). About half of subjects report throat irritation or coughing (138). Whether some patients use nicotine inhalers for long periods or have withdrawal upon cessation of inhaler use has not been tested.

5) Lobeline. Major side effects, including abuse/dependence, from lobeline have not been reported (149).

e. Implementation

1) Indications. How to decide to whom to give nicotine replacement therapy is debatable (48, 60, 88, 101, 115, 153, 154). Nicotine gum (especially the 4-mg dose) and nicotine nasal spray are more helpful in highly nicotine-dependent patients (as measured by the Fagerstrom scale); however, even patients who are less dependent appear to obtain some benefit from nicotine gum (12). The package insert for nicotine patches states they are to be used only by those who smoke 15 cigarettes per day or more. No such minimum is given for nicotine gum. On the other hand, nicotine patches are beneficial to both highly and less nicotine-dependent smokers (12, 115, 127, 151). Whether highly nicotine-

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dependent smokers would most benefit from nicotine gum, patch, or nasal spray has not been tested (113).

Number of cigarettes per day, presence of significant withdrawal during prior quit attempts, and time to first cigarette have also been proposed as indicators for the use of nicotine replacement therapy, but there are no data on the utility of these indicators. Some have suggested that nicotine replacement therapy be used only if the patient is enrolled in behavior therapy; however, the data clearly show that nicotine replacement therapy is effective in the absence of behavior therapy (see section III.F.2.b.3).

In summary, nicotine replacement should be considered in all smokers who have seriously tried to quit on their own and failed [III]. Use of nicotine replacement in smokers with cardiovascular disease or who are pregnant is discussed in sections V.B.2. and V.C.3., respectively. Although nicotine gum and patches are available over the counter, psychiatrists still need to be involved in their use by encouraging use when appropriate, supplementing package instructions, and providing adjunctive psychiatric management and, when appropriate, psychosocial and other pharmacological therapies.

2) Pretreatment evaluation. Some have suggested precessation cotinine level is a useful benchmark to examine the percent of nicotine replaced by nicotine medication therapy and thus make decisions on whether higher doses should be used. Whether this improves treatment is controversial (53).

3) Length of treatment. Most treatment optimally lasts 4–6 weeks before tapering [III]. Some have advocated longer-term use of nicotine replacement therapy and even a nicotine maintenance program. Two prospective trials differed in whether longer treatment with nicotine gum produced higher abstinence rates (155, 158). A recent meta-analysis of nicotine patches did not find that longer treatment was associated with higher quit rates (133).

3. Antagonists

a. Goals. The goal of antagonist therapy is to prevent cigarettes from producing positive reinforcing and subjective effects.

b. Mecamylamine. Mecamylamine is a noncompetitive blocker of both central nervous system and peripheral nicotinic receptors (124, 157, 158) that decreases the positive subjective effects from cigarettes (157, 158). When mecamylamine is given to smokers who are not trying to stop smoking, they initially increase their smoking in an attempt to overcome the blockade produced by mecamylamine (157, 158). Mecamylamine does not precipitate withdrawal in humans, perhaps because it is an indirect blocker (157, 158).

Early studies suggested some short-term efficacy with mecamylamine, but the high doses used produced significant dropout rates because of side effects (157, 158). Side effects included abdominal cramps, constipation, dry mouth, and headaches. Based on a theory that combined blockade and agonist therapy might be beneficial (159), a recent study combined low doses of mecamylamine and nicotine patch and produced a significant increase in long-term efficacy with few side effects (160).

Antagonists have not been effective in opioid drug dependence because of compliance problems (161). Smokers tend to be more compliant than opioid abusers; thus, nicotine antagonists might be effective. Behavioral programs to insure compliance similar to those used with alcohol and cocaine dependence might also be helpful (161). In summary, mecamylamine lacks sufficient evidence to be recommended but is considered promising.

c. Naltrexone. Naltrexone is a long-acting form of the opioid antagonist naloxone. The rationale for using naltrexone for smoking cessation is that the performance-enhancing and other positive effects of nicotine may be opioid mediated (162). Most, but not all, studies have found that naltrexone increases smoking (interpreted again as an attempt to overcome blockade) (123, 163). There are no data on naltrexone as a cessation treatment nor on what happens to cigarette use in alcoholics treated with naltrexone. The few side effects from naltrexone include elevated liver enzymes, nausea, and blockade of analgesia from narcotic pain relievers (123). In summary, at this time, naltrexone lacks sufficient evidence to be recommended.

4. Medications that make intake aversive

a. Goal. Medications in this class produce unpleasant events when the patient ingests the medication. Disulfiram treatment for alcoholism (164) is the most widely known example of this class.

b. Silver acetate. This medication combines with sulfides in tobacco smoke to produce a bad taste. Silver acetate has been tested as a gum and as a pill; neither form has consistently been shown to be effective (3, 56, 123, 149). In fact, the FDA recently pulled silver acetate from over-the-counter sales because of lack of efficacy (149). As with disulfiram, compliance appears to be quite poor; thus this treatment might be effective if used in conjunction with a behavioral compliance program. The major side effect of concern is argyrism (silver poisoning), which produces discoloration of skin. This appears to be very rare at the doses used for smoking cessation (149). In summary, silver acetate lacks sufficient evidence to be recommended.

5. Medications that mimic nicotinic effects

a. Clonidine. Clonidine is a postsynaptic α_2 agonist that dampens sympathetic activity originating at the locus ceruleus (123, 125, 165). It appears to have some efficacy for alcohol and opioid withdrawal and thus was tried with nicotine withdrawal as well (123, 125). Several clinical trials used oral or transdermal clonidine in doses of 0.1–0.4 mg/day for 2–6 weeks with and without behavior therapy. Three meta-analytic reviews

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reported clonidine doubles quit rates (56, 125, 165), but a fourth disagreed (3).

The most common side effects of clonidine are dry mouth, sedation, and constipation (165). Postural hypotension, rebound hypertension, and depression are rare with smoking cessation treatment (165). Several studies have suggested clonidine is more effective in women than in men; however, many studies have failed to find this association (165).

Although clonidine appears to increase quit rates similar to that of nicotine replacement therapy, the quantity and quality of the scientific studies on clonidine are less than that for nicotine replacement therapy. Nevertheless, clonidine may be an alternative for smokers who prefer not to receive nicotine and for smokers who have failed nicotine replacement therapy [II].

b. Anxiolytics. Anxiety is a prominent symptom of nicotine withdrawal (166). In addition, smoking decreases some measures of anxiety and may reduce stress-induced anxiety (166); thus, temporarily replacing the anxiolytic effects of nicotine with another medication during the first weeks of cessation might make cessation easier. Diazepam appears to decrease tobacco withdrawal, but in a well-conducted long-term clinical trial, diazepam did not increase abstinence (123). β Blockers can act as anxiolytics. Placebo-controlled trials of metoprolol, oxprenolol, and propranolol have not found that they decrease craving or increase abstinence rates (123). Older trials found that the nonbenzodiazepine anxiolytics meprobamate and hydroxyzine were not effective for smoking cessation (123). In summary, the above anxiolytics do not have sufficient evidence to be recommended.

Buspirone is a serotonergic agonist, which acts as an anxiolytic but produces minimal, if any, sedation, abuse potential, or physical dependence. Major side effects to buspirone are rare. Some short-term trials have reported that buspirone appeared to reduce nicotine withdrawal, but others have failed to find this (123). Buspirone improved short-term smoking cessation rates in unselected smokers and improved abstinence in high-anxiety smokers (123). Because of its favorable side effect profile and some evidence of efficacy, buspirone is classed as a promising therapy.

c. Antidepressants. A past history of depression and dysphoria prior to, at the onset of, or during smoking cessation predicts failure to stop smoking; thus, antidepressants might be useful in helping smokers with these problems stop smoking (2, 167). In the only published long-term clinical trials, imipramine had no effect on smoking cessation (123), but a more recent trial of nortriptyline was positive (168). Two trials with fluoxetine were completed some time ago but the results were never published or presented (123). Short-term trials with doxepin, tryptophan, and bupropion in unselected groups of smokers have also reported promising results (123).

Many antidepressants have substantial side effects and a long delay in efficacy; thus, these treatments may not be acceptable to the general population of smokers. A more focused approach might be treatment with antidepressants prior to cessation in the 30%–40% of smokers with a past history of depression or in smokers who are dysphoric at the time of smoking cessation. In summary, antidepressants are considered a promising treatment.

d. Stimulants. The goal here is to replace the stimulant effects of nicotine (e.g., improved energy and concentration) with a medication in the first weeks of cessation. The one long-term study of a stimulant found that amphetamines did not increase abstinence (123). A recent uncontrolled trial suggests methylphenidate decreases tobacco withdrawal (169). Finally, if stimulants were found to be effective, whether dependence on the stimulant occurs would need to be examined. In summary, stimulants lack sufficient evidence to be recommended.

e. Anorectics. Anorectics were used initially to combat postcessation hunger and weight gain because these are two of the most widely cited reasons for difficulty in stopping smoking (77). Short-term trials of women with weight concerns reported that both fenfluramine and phenylpropanolamine reduced postcessation weight gain and some withdrawal symptoms and increased abstinence (123). The results are intriguing, given the data that controlling weight by adding a dieting component to a multicomponent program worsens rather than improves abstinence rates (78, 79). Fenfluramine and phenylpropanolamine have few side effects. In summary, both of these medications lack sufficient evidence to be recommended but are considered promising.

6. *Sensory replacement*

Black pepper extracts (170), capsaicin (171), denicotinized tobacco (172), flavorings (173), and regenerated (denicotinized) smoke (174) all decrease cigarette craving or withdrawal or substitute for the satisfaction from cigarettes in laboratory tests. A citric acid inhaler has been developed and showed some promise in two clinical trials (175, 176). As expected, this treatment has very few side effects. Since sensory treatments could be used not only as a stand-alone therapy but also as an adjunct to traditional pharmacotherapies, this appears to be a promising treatment.

7. *Other medications*

Sodium bicarbonate has been used to decrease the rate of urinary elimination of nicotine and thereby decrease withdrawal symptoms (123). ACTH has been used to decrease postcessation hypoglycemia (123). Anticholinergics have been used to reduce a hypothesized cholinergic rebound upon smoking cessation (123). Dextrose has been used to prevent smokers from mislabeling hunger as nicotine craving (123). Homeopathic remedies and nutritional supplements have also been proposed. For all of these treatments, the basic rationale and mechanism of action is suspect and controlled trials of long-term abstinence are lacking (123); thus, all lack sufficient evidence to be recommended.

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8. Acupuncture

One common rationale for the use of acupuncture for smoking cessation is that acupuncture can release endorphins that assist in cessation. Controlled studies comparing advice versus sham acupuncture sites do not consistently show efficacy (3, 57, 177, 178); thus, this treatment lacks sufficient evidence to be recommended.

9. Devices

Filters have been used to help smokers gradually reduce the amount of smoking. Short-term studies show smokers compensate for such changes to some extent (90, 179). The few studies of the efficacy of filters are inconclusive (90, 179). A small computer has been developed that uses self-monitoring data to then program a set of times to smoke. The computer gradually eliminates cigarettes by increasing the inter-cigarette interval. There are no published controlled studies with the device. In summary, there is not sufficient evidence to recommend devices as a treatment.

G. COMBINED PSYCHOSOCIAL AND SOMATIC THERAPY

The goal of combined therapy is to provide treatment for withdrawal and to concurrently develop antismoking skills. Most meta-analyses and most experimental trials indicate that, unlike other dependencies, formal psychosocial treatment is not essential to obtain benefits from somatic therapies. In other words, nicotine replacement therapy (34, 56–58, 92, 115, 124, 126, 127, 129, 133, 146) and clonidine (125, 165) increase quit rates by a factor of 1.5 to 2.0, both when given with brief advice plus follow-up (i.e., similar to psychiatric management) and when given with formal psychosocial therapy.

Although nicotine replacement is effective without formal psychosocial therapy, it is important to note that in most studies, combining nicotine replacement with a behavior therapy gives substantially higher quit rates than either behavior therapy or nicotine replacement alone (34, 53, 129). Thus, combined therapy is a recommended treatment [I].

IV. FORMULATION AND IMPLEMENTATION OF A TREATMENT PLAN

A. ADULT PATIENTS WHO ARE BEING SEEN BY PSYCHIATRISTS AND WHO CURRENTLY USE TOBACCO

1. Introduction

There are only a handful of controlled studies of treating smoking among psychiatric patients (2, 34, 180); thus, much of what is recommended in this section is based on treating smokers who do not have a current psychiatric disorder plus the general principles of treating psychiatric patients. The guidelines that follow are similar to those offered by others for psychiatric patients who smoke (63, 68, 69, 181).

2. Assessment

Assessment of psychiatric patients focuses on five points [II]. First, is the patient presently motivated to quit smoking? If not, then motivational strategies should be used. If the smoker is ready to quit, then a concrete discussion of cessation procedures should occur. Second, are there any psychiatric reasons for concern about whether this is the best time for cessation; e.g., is the patient about to undergo a new therapy, is the patient presently in crisis, or is there a problem that is so pressing that time is better spent on this problem than on cessation [II]? Third, what is the likelihood that cessation would worsen the nonnicotine psychiatric disorder [II] (2) and can that possibility be diminished with frequent monitoring, use of nicotine replacement therapy, or other therapies? Fourth, what is the patient's ability to mobilize coping skills to deal with cessation [II]? If coping skills are low, would the patient benefit from individual or group behavior therapy? Fifth, is the patient highly nicotine-dependent or does the patient have a history of relapse due to withdrawal symptoms or increased psychiatric symptoms [I]? If so, which medication might be of help?

3. Psychiatric management

a. Increasing readiness/motivation. Since it appears that most psychiatric patients are not ready to make a quit attempt (44), most often treatment will consist of enhancing motivation and dealing with anticipated barriers to cessation (61). Fears of withdrawal symptoms or of worsening psychiatric problems may be dealt with by problem solving, increased monitoring by the therapist, and behavior therapy or nicotine replacement [III].

b. Stepped care approaches. Since the large majority of smokers quit on their own or with minimal treatment (27, 182), most existing algorithms/guidelines rely on a stepped care approach with minimal interventions early on and more intensive interventions for those who are not able to stop with minimal interventions (48, 88, 153, 154). There are three issues to consider with this approach: 1) Most smokers who quit on their own re-

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quire several attempts before they succeed (27); thus, any success later in the algorithm cannot be attributed to the specific treatment being given at that point. 2) Early cessation of smoking can prevent much of the devastating consequences of smoking (18); thus, delaying delivering a treatment known to be effective could allow a serious, irreversible consequence of smoking (e.g., an acute myocardial infarction) to occur. 3) The notion that most smokers can quit on their own or will need only minimal treatment is based on research on smokers without a history of psychiatric problems (27). Smokers with psychiatric problems appear to be 2–3 times less likely to successfully stop smoking than smokers without psychiatric problems (2, 8, 33); thus, psychiatric patients require more intensive interventions earlier on [II].

c. Timing. It may be helpful to have smoking cessation listed as a goal on the master treatment plan for smokers [I]. When and how cessation advice is best delivered must be determined by the patient's status; e.g., smoking cessation is not likely to be successful when the patient is in crisis [III]. The best time for cessation would appear to be when the patient is psychiatrically stable, there are no recent or planned changes in medications, and no urgent problems take precedence [III].

d. Monitoring. Cessation appears to exacerbate psychiatric symptoms, and these symptoms undermine smoking cessation in a small subset of patients (2); thus, patients with a present or past psychiatric history are contacted optimally 2–3 days postcessation and often thereafter to assess mood, problems, etc. [II]. The blood levels of many psychiatric medications increase substantially when patients taking such medications stop smoking, and these increases could worsen side effects or cause toxicity (table 5) (8); thus, blood levels and medication side effects should be monitored [II].

4. Use of psychosocial treatments

Although brief interventions, self-help, and supportive therapy have been shown to be effective with general medical patients, such minimal therapies may not be sufficient in patients with psychiatric problems. In addition, psychiatric patients often have fewer social supports, coping skills, etc. These two considerations suggest behavioral therapy should be considered even in the early quit attempts for these patients [II]. Since many psychiatric patients have experience with individual or group therapy, patient preferences should be considered in choosing between the two [III]. If the patient has specific problems that undermine cessation (e.g., problems with assertiveness), the therapist might work on this issue in individual therapy while the patient continues a group therapy [III].

5. Use of pharmacotherapy

Since psychiatric patients appear to have more withdrawal symptomatology when they stop smoking (2), use of nicotine replacement therapy even in early cessation attempts is recommended [II]. Given that compliance with nicotine gum is difficult (183), nicotine nasal spray has abuse potential (15), and clonidine has frequent side effects (165), the nicotine patch is recommended as the usual initial pharmacotherapy [I]. Although many psychiatric patients smoke large numbers of cigarettes and inhale cigarette smoke deeply (8), using higher-than-normal doses of nicotine for heavier smokers has not consistently been shown more effective (53). However, supplementation of nicotine patch with ad-lib use of nicotine gum appears to help patients over the rough times and should be considered [II] (119).

Those patients who smoke fewer than 15 cigarettes per day are candidates for starting with an intermediate rather than high-dose patch or for using nicotine gum instead [II] (151). Whether the 24- or 16-hour patch is better is debatable (133, 151). Twenty-four-hour patches may better relieve morning craving but appear to cause insomnia (131, 132). Longer durations of patch therapy have not been found more effective (133); thus, a 6- to 12-week duration of therapy is recommended [II].

If the patient has a preference for nicotine gum, then the gum is best used with scheduled dosing (e.g., 1 piece of gum/hour) rather than ad-lib dosing, and the 4-mg dose is recommended for heavy smokers (more than 25 cigarettes/day) or more nicotine-dependent smokers [II] (143, 184, 185). In any of the situations in which nicotine gum is used, strong encouragement to comply with use recommendations is necessary [II]. The optimal duration of nicotine gum therapy is debatable (113). Clinically, some patients appear to require long durations of treatment; i.e., 6 months or longer. Given the lack of medical harm from nicotine gum and that almost all smokers eventually stop using the gum (41), patient preference for duration of gum use should be the major determinant for duration of treatment [III]. Some clinicians have suggested that some smokers will need nicotine maintenance for life. Given the absence of empirical data on this, proactive encouragement of maintenance is not recommended.

If the patient has a strong objection to nicotine replacement therapy, clonidine may be used [II]. Clonidine delivered via patch therapy may improve compliance. Usually 0.1–0.4 mg of clonidine per day is needed [II] (125, 165). If this therapy is used, interactions of clonidine side effects (e.g., sedation) with psychiatric status should be monitored [II] (165).

Among patients with a past history of a psychiatric disorder but who are no longer taking psychiatric medications or in active psychotherapy, restarting psychiatric medications or psychotherapy prior to cessation may dampen withdrawal problems and prevent remission of the psychiatric illness (2, 167). Although the efficacy of this strategy has not been tested, if the patient or physician believes psychiatric symptomatology has precipitated relapses in prior cessation attempts, reinstitution of psychiatric treatment should be considered (2).

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B. SMOKERS WHO HAVE FAILED INITIAL TREATMENT

1. Definition of group

This group is composed of smokers who have failed a trial of a known effective formal therapy (e.g., behavior therapy or nicotine replacement).

2. Assessment

a. Adequacy of prior therapy. As with treatment failures with other psychiatric disorders, a first consideration is the adequacy of prior treatment [III]. How many sessions of behavior therapy were attended? What was the quality of the behavior treatment in the last quit attempt? What were the doses of gum or patch used? What was the duration of therapy? What was the level of compliance with the psychosocial or somatic therapy? How long did the patient remain abstinent?

b. Cause of relapse. Another important consideration is to determine the perceived cause of the relapse [III]. Was the relapse due to uncontrolled withdrawal symptoms, environmental stressors, alcohol use, negative or positive mood, or being around other smokers? Were there factors (e.g., fatigue, life disappointments, family/social stressors) that undermined cessation?

c. Motivation to stop. The clinician should encourage the patient to try to quit again, and if the patient agrees, a new quit date should be set [II]. What was the patient's satisfaction with prior treatments? What did he or she learn from prior failures? If the patient is not ready to try again, what are his or her fears and what are the barriers to attempting again? What changes does the patient think need to be made before another attempt is made?

d. Search for comorbidity. Most smokers have not been assessed for psychiatric or alcohol/drug abuse problems initially and such problems interfere with cessation (2, 167); thus, screening for such disorders is indicated [II]. In prior studies, 15%–20% of heavy smokers have current and up to 35% have past alcohol problems (186). Similarly, 40% of smokers seeking treatment have a past history of depression (2, 167).

3. Psychiatric management/use of psychosocial and pharmacological treatments

a. Prior treatment inadequate. If the prior treatment appeared appropriate but was inadequately implemented, the therapy may be repeated with changes to insure the fidelity of therapy, compliance, adequate dose and duration, etc. [III].

b. Prior treatment adequate. If the prior treatment was appropriate and adequate, the psychiatrist should attempt to determine whether the relapse was due to withdrawal symptoms versus nonwithdrawal causes.

1) Relapse due to withdrawal. If the prior relapse appeared to be caused by withdrawal symptomatology and the patient has not previously been treated with nicotine replacement, nicotine patch therapy is appropriate [I]. If the patient has been adequately treated with nicotine patch therapy, then clonidine [II], nicotine patch plus nicotine gum [II], nicotine nasal spray [II], or higher-dose nicotine patch [III] may be considered. Simply re-treating with nicotine patch therapy is not very effective (135, 148, 187, 188). Use of nicotine nasal spray is recommended because this delivery mode produces a more bolus-like effect that might better relieve withdrawal and craving [III] (136).

Use of nicotine nasal spray initially and then switching to nicotine patch or the concomitant use of nicotine nasal spray and nicotine patch have also been proposed (119) but have not been tested. The rationale for the use of clonidine is simply to try a medication from a different class. A final possibility is symptomatic treatment based on the type of withdrawal symptoms (e.g., antidepressants for withdrawal-induced depression). Although logical, this strategy has not been adequately tested.

2) Relapse due to nonwithdrawal stressor. If the smoker has relapsed due to a stressful life event and has not previously been treated with behavior therapy, it should be considered. If the patient has already had behavior therapy, two choices are available: 1) more intensive behavior therapy [III] or 2) behavior therapy with a different content or format; i.e., group therapy, individual therapy, combined individual and group therapy, or involvement of family members [III]. Whether these treatments would be effective for those who have failed prior behavior therapy has not been tested. Switching to nonbehavioral psychosocial treatments (e.g., hypnosis or 12-step therapy) is not recommended because there is no empirical support for their efficacy.

3) Combined therapy. Sometimes it is difficult to distinguish withdrawal versus nonwithdrawal causes of relapse. In this case, the patient may be a candidate for combined pharmacological and behavior therapy (128, 129) [III].

4) Referral. When the treating psychiatrist does not have the knowledge necessary to implement the treatments outlined here or if the strategies are administered and the smoker is not able to quit, referral to someone who specializes in treating nicotine dependence should be considered [III].

5) Inpatient programs. An inpatient model for smoking cessation has been described (189) and appears to produce high quit rates, especially given the highly nicotine-dependent smokers enrolled. There are no controlled trials that substantiate this at the current time.

C. TREATMENT OF SMOKERS ON SMOKE-FREE WARDS

1. Introduction

This section focuses on psychiatric patients on smoke-free wards, but the same principles apply to smokers on general medical wards seen in consultation and to smokers in smoke-free nonmedical settings; e.g.,

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residential care settings. Controlled studies of treating nicotine withdrawal symptoms on medical or psychiatric inpatient wards have not been published; thus, the recommendations below are based on treating withdrawal in outpatient settings (16, 17).

2. Assessment

a. Withdrawal. Assessment focuses on reports of a history of withdrawal symptoms in prior hospitalizations, withdrawal during prior voluntary quit attempts, or significant fear of withdrawal [III].

b. Smoking cessation. An inpatient stay may be an opportune time for initiating treatment for nicotine dependence (e.g., because of intensity of exposure to medical staff, diagnosis of medical condition, removal from usual smoking cues). It may therefore be helpful to include smoking cessation on the master treatment plan whenever relevant. Smokers should be assessed for their readiness and motivation for change as described in section III.C.1. [I] (39). Those considering quitting should be asked about their interest in using the temporary abstinence of the smoke-free unit as the beginning of an attempt to stop smoking permanently [III].

3. Psychiatric management

a. System issues. It is very difficult to motivate inpatients to stop smoking unless the unit is smoke-free (69, 190); thus, a smoke-free psychiatric unit is recommended [I]. Although many inpatient units have been concerned about going smoke-free, the large majority have found it less difficult than anticipated (69, 190). Studies before and after institution of smoke-free units indicate no increases in aggression, disruption, discharges against medical advice, use of medications or restraints, or admission refusals (190). One of the most important issues is to prevent psychiatric staff who smoke from either purposefully or inadvertently undermining smoke-free restrictions. Permitting staff to smoke while on the inpatient unit or in contact with patients may increase the difficulty for patients who are trying to quit.

Giving special off-ward privileges to allow patients to smoke or labeling off-ward passes as "smoking breaks" implicitly condones smoking (69, 190). In addition, there are risks in allowing the patient smoking breaks; e.g., if the patient has suicidal ideation or a history of eloping or acting out on passes [III]. Policies that provide breaks for both smokers and nonsmokers (on the same schedule) may be preferable to policies that provide smokers with extra passes. Other recommendations for implementing a smoke-free unit are discussed in recent reviews (69, 190).

b. Patient education. Patients need to be educated about the rationale for a smoke-free unit; i.e., it is not to force patients to stop smoking but to prevent secondhand smoke exposure to other patients and to be consistent with the institution's goal to encourage healthy behaviors [II] (69, 190). Patients should also be educated about the goal of treatment; i.e., to reduce withdrawal symptoms and, if patients are interested, to help them begin a cessation attempt [II]. Many patients are unaware of the valid symptoms of nicotine withdrawal and their time course; thus, education about these can be helpful [II] (69, 190).

c. Monitoring. Patients need to be monitored for changes in psychiatric symptoms, as withdrawal can worsen anxiety, insomnia, concentration, and weight gain and can cause clinically significant increases in the levels of several psychiatric medications [III] (tables 4 and 5) (2, 8). For example, many alcoholics smoke. Thus, during alcohol detoxification on a smoke-free ward, how much of the irritability, anxiety, insomnia, restlessness, difficulty concentrating, and depression is due to alcohol versus nicotine withdrawal is unclear. Although nicotine withdrawal is thought to be milder, there is substantial between-person variability such that some alcoholic smokers have nicotine withdrawal symptoms that are more severe than their alcohol withdrawal symptoms (191). Similarly, when patients with schizophrenia are hospitalized and given higher doses of medications, any increases in restlessness could be due to nicotine withdrawal rather than neuroleptic-induced akathisia. Finally, cessation of smoking can cause dramatic increases in blood levels of some medications; e.g., clozapine levels can increase 40% when smokers are deprived of nicotine (192).

4. Use of psychosocial treatments

The efficacy of psychosocial treatments for withdrawal symptoms has not been tested (16); however, the clinical experience of the Work Group on Nicotine Dependence suggests several strategies [III]. Relaxation tapes can be used to alleviate anxiety. Anger can be averted by temporarily avoiding interactions. Insomnia can be decreased by improving sleep hygiene. Weight gain can be combated by increasing activity. Distraction and activities aimed at keeping busy can be used to get through craving episodes. Support groups for those going smoke-free and support from family and significant others for going smoke-free can be helpful as well.

5. Use of pharmacological therapies

Nicotine withdrawal during hospitalization is often not as severe as anticipated because of the absence of smoking cues, the distraction of the primary problem, the effects of medications, etc. Thus, prophylactic pharmacotherapy should be considered only when patients complain of withdrawal symptoms or if withdrawal signs are observed [I]. Exceptions to this rule would be those patients who are so concerned about nicotine withdrawal that they will not accept hospitalization without treatment for withdrawal. In this scenario, given the low risk of nicotine replacement, prophylactic treatment with nicotine replacement may have advantages over giving extra passes for smoking breaks [III]. The advantages of nicotine gum include the patient's

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ability to self-titrate nicotine dose and to stop using it immediately before intermittent smoking (e.g., during passes) [III]. In addition, many patients find that only a few pieces of gum per day are sufficient to prevent withdrawal symptoms (69, 190). The nicotine patch has the advantage of improved compliance and stable nicotine replacement. This may be especially advantageous in differentiating nicotine withdrawal from other psychiatric symptoms (8). One disadvantage of nicotine gum and patch is that patients may smoke while using them [III]. Although not desirable, this appears to be unlikely to produce significant adverse effects (193).

V. CLINICAL FEATURES INFLUENCING TREATMENT

A. PSYCHIATRIC DISORDERS

1. *Alcohol/drug use/abuse*

Some 15%–20% of heavy smokers have current alcohol dependence or abuse (34). Smokers who have current alcohol/drug problems are unlikely to stop smoking permanently without overcoming the alcohol/drug problems (34); thus, in most cases, alcohol/drug abuse problems should be treated prior to or concurrent with the treatment of nicotine dependence [II]. About 80% of alcohol/drug abusers who are in treatment are smokers (1, 34). About half of such smokers are not presently interested in stopping smoking (34) and thus would benefit from treatments to increase motivation and readiness to change [II]. For the other half interested in stopping, whether it is best for them to stop smoking at the same time as they stop alcohol/drug use or to stop smoking immediately after or long after stopping alcohol/drug use is unclear (34). One rationale for stopping smoking at the same time as stopping alcohol/drug use is that use of each substance serves as a cue for use of the other substance; thus, by stopping both substances, such cues are eliminated. The major rationale for stopping smoking after stopping drinking/drug use is that often stopping drinking is a more urgent concern and that stopping two drug dependencies at the same time is just too difficult. Given the absence of empirical data, patient preferences for when to stop smoking in relation to alcohol/drug abuse treatment should be respected [III].

A common concern is that smoking cessation will cause relapse to alcohol/drug use. Most of the available data do not support this (34). In two studies, 80%–85% of recovering alcoholics reported no increased craving for alcohol nor did they relapse to alcohol use when they stopped smoking (2, 34). In fact, correlational studies suggest smoking cessation may decrease the probability of relapse to alcohol (34). However, frequent monitoring during smoking abstinence is recommended in this group to help prevent the other 15%–20% from relapsing to drinking during smoking cessation [III]. Although not empirically tested, smokers who have a history of increased desire for alcohol during abstinence from smoking could either reenter or intensify ongoing therapy for alcoholism or could be prescribed a course of disulfiram [III]. There are very little data on how to tailor a smoking cessation program to the specific needs of recovering alcoholics; e.g., whether such patients need a more intensive program, would do better in a 12-step or behavior therapy program, or would need higher-than-normal dose nicotine replacement because they are more nicotine dependent (34). However, recent studies suggest treatment of smoking may be effective either during or after treatment for alcoholism [III] (34, 194).

2. *Depression*

Among patients seeking smoking cessation treatment, 25%–40% have a past history of major depression and many have minor dysthymic symptoms (2, 167). Since both have been shown to predict poor smoking cessation rates and since one study reported that 33% of those with a history of bipolar disorder and 18% of those with a history of unipolar depression relapsed to depression during smoking cessation (26), the psychiatrist should consider starting or restarting psychotherapy or pharmacotherapy for depression in patients who state that depression intensified with cessation or that cessation caused depression [III]. This recommendation is based on the results of recent trials that found that cognitive behavioral therapy for depression and antidepressants improved smoking cessation rates in those with a past history of depression or who had symptoms of depression (168, 180, 195). Finally, for a smoker with a past history of depression currently taking antidepressant medication, it is important to note that some antidepressant levels will increase with smoking cessation [II] (8).

3. *Schizophrenia*

Patients with schizophrenia who smoke are often not interested in stopping (33, 44, 196). Thus, strategies to motivate these patients to commit to quit are especially important [III]. When patients with schizophrenia do try to stop, many are unsuccessful (33); thus, intensive treatments are appropriate even with early attempts [III]. The high prevalence of alcohol and illicit drug abuse in patients with schizophrenia (33) can interfere with smoking cessation [II]. The blood levels of some antipsychotics can increase dramatically with cessation and nicotine withdrawal can mimic the akathisia, de-

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pression, difficulty concentrating, and insomnia seen in patients with schizophrenia (see section IV.C.3.c.)

4. Other psychiatric disorders

There is insufficient information to make specific recommendations about tailoring treatment of smoking cessation to the needs of smokers with other psychiatric disorders. In general, when psychiatric patients make an attempt at smoking cessation, they should be followed closely to monitor for more severe nicotine withdrawal, exacerbation of their psychiatric disorder, and possible side effects due to cessation-induced increases in medication levels [III] (8).

B. CONCURRENT GENERAL MEDICAL DISORDERS

1. General management

Often, psychiatrists are asked to see general medical patients in consultation. In addition, many psychiatric patients who smoke have smoking-induced medical illnesses. In fact, the onset or diagnosis of a smoking-related medical illness provides an opportunity for motivating the patient to make a quit attempt (73). Smokers who have recently been diagnosed with a tobacco-related illness (e.g., a heart attack) have a substantially greater success rate at smoking cessation (73). Since many of these patients will quit on their own without treatment (73), a stepped-care approach is appropriate with these patients [III] (48). In this approach, patients are given minimal therapies initially unless there are particular reasons to use more intense interventions (e.g., current active alcohol dependence). With this approach, the clinician needs to follow these high-risk patients closely to initiate treatment promptly because many patients will relapse after minimal treatment [I] (48, 73). If minimal treatment fails, a more intensive treatment should be tried.

If the patient is hospitalized for a medical problem when he or she decides to stop smoking, withdrawal may not be a problem while the patient is in the hospital; thus, nicotine replacement therapy may not be necessary [III] (48, 73). However, many patients find that withdrawal symptoms occur upon return to their natural environs (16); thus, these patients should be followed very closely after discharge to determine whether nicotine replacement therapy is indicated [I].

In patients with general medical problems, it is important to remember that smoking interferes with administration of many treatment medications, increases risks of anesthesia and surgery, and impairs healing (42). That smokers are at very high risk for lung cancer, chronic obstructive lung disease, heart disease, ulcers, etc., needs to be considered in all medical evaluations (61).

Finally, several childhood illnesses are associated with secondhand smoking (e.g., upper respiratory illnesses) (22, 23). Pointing out this relationship is often a motivator for patients to stop smoking.

2. Cardiovascular disease

Patients either at risk for or who already have cardiovascular disease should be made aware of three facts to increase their motivation to stop smoking [II]: 1) The risks of cardiovascular disease decrease markedly in the first year after smoking cessation and are near normal by 5 years postcessation (197). 2) Stopping smoking also substantially increases post-myocardial-infarction survival (197). 3) Stopping smoking is much more important than changing diet, weight, or exercise (197). The one anecdotal observation of heart attacks occurring while using nicotine patches has been refuted by empirical studies that show that the nicotine patch is safe in patients with stable cardiac disease (193).

3. Pulmonary disease

Smoking cessation improves many respiratory symptoms (sometimes cough is transiently worse in the first few weeks) (16) but causes no or little reversal in pulmonary function (197, 198). In most cases, cessation does stop the accelerated decline in lung function with chronic obstructive pulmonary disease (197). Smokers who persist in smoking despite pulmonary disease appear to be highly nicotine dependent with a high incidence of alcohol problems (64, 199); thus, treatment with nicotine replacement therapy and screening for alcoholism are especially important in this group [III]. Also, smoking cessation increases theophylline levels up to 40% (42). Some have suggested pulmonary function changes due to smoking can be used as motivators in such patients, but this has not been well tested (50, 55).

4. Cancer

The risk for cancer declines with increasing duration of abstinence from smoking (197). In those who already have cancer, cessation improves the quality of life (73, 197); thus, cancer patients should still be advised to stop smoking [I].

C. DEMOGRAPHIC AND PSYCHOSOCIAL VARIABLES

1. Elderly

The rates of smoking in those over 65 are lower than in younger persons (15%–20%) (200). Cessation in this age group is still beneficial both in terms of the length and quality of life (197, 200). There are programs tailored to the elderly, but these have not been well tested to see if they are better than nontailored programs (200, 201). Behaviorally based programs appear to be effective and are recommended with the qualification that cognitive deficits and depression are common in this group [II]. The elderly do not appear to have greater side effects with nicotine replacement therapy (202), and this treatment should be considered [II].

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2. *Youth*

Despite a large public health effort, the prevalence of smoking in teens has actually increased in the last 3 years (Monitoring the Future, 1995, unpublished data). This increase appears to be associated with tobacco advertising (5). Although policy initiatives focused on illegal sales, taxation, and vending machines are essential to combating smoking among youth, providing treatment for smoking cessation also could be helpful. Young smokers appear to develop nicotine dependence fairly quickly, in that many have withdrawal when they try to quit, and most find it difficult to stop (5). Smoking is highly correlated with alcohol/drug problems in youth (37); thus, screening for comorbidity in this group appears important. There are few studies of smoking cessation treatments for adolescents, and none that show high long-term quit rates (5). However, the Work Group on Nicotine Dependence found no reason to believe that the psychiatric management strategies (table 7) and the psychosocial treatments (table 8) effective in adults would not be effective in youth; thus, these are recommended [III]. Whether nicotine replacement therapy would be of help in this group has not been tested (5); however, based on the results from adults, youth who are nicotine dependent (e.g., have withdrawal symptoms upon cessation) should be considered for nicotine replacement therapy [III].

3. *Gender*

Although earlier studies suggested women were less likely to succeed in stopping smoking, more recent data suggest women are quitting at same rate as men (203). The factors that undermine cessation in women appear to be depression, social support, and weight gain (203). Some data have suggested men do better with nicotine replacement therapy (203) and women do better with clonidine (165); however, these findings have not been consistently replicated. Whether women have more withdrawal symptoms and are more influenced by social support than are men is also unclear (204). There are no replicable empirical data on how to tailor smoking treatments to the needs of women (203).

Smoking during pregnancy is associated with increased perinatal complications and low-birth-weight babies (205). How much of the low birth weight is due to nicotine-induced vasoconstriction of the placental artery or carbon monoxide-induced hypoxemia is unclear (205, 206). If a woman stops smoking within the first two trimesters, her risk of having a low-birth-weight child is near normal (205). Female smokers who do not stop early on in pregnancy appear to be highly nicotine dependent (24). Behavior therapy tailored to this group appears to be effective and is recommended [II] (73, 205). Weight gain concerns and depression may undermine resistance to cessation in this group and need to be addressed [III] (73, 205). Many pregnant smokers relapse immediately postpartum (73, 205); thus, special emphasis on maintaining abstinence postpartum is indicated [II].

The use of nicotine replacement therapy in pregnancy is debatable (23, 206). Recent preclinical data suggest nicotine itself could adversely affect the developing central nervous system (207); however, the level of nicotine to which the fetus is exposed is much lower from nicotine gum and patch than from cigarettes. Nicotine replacement therapy should still be considered in pregnant women who have tried to stop during their pregnancy but have not been able to do so because of withdrawal symptoms [III]. If nicotine replacement is used, the woman should understand the benefits and risks of nicotine replacement therapy, and the clinician should consider a lower dose and a shorter duration of treatment to reduce fetal exposure to nicotine [III].

4. *Race/ethnicity*

In examining the association of race, culture, or ethnicity with nicotine and other drug dependence, it is important to differentiate sociodemographic factors (e.g., income, education) from race/ethnicity factors (208). Blacks are less likely to initiate smoking, smoke fewer cigarettes per day (11), and appear to be less likely to become nicotine dependent (31), but have higher cotinine levels and are less likely to stop smoking than whites (208). There are no replicable empirical data on how to change the form or content of cessation therapies for blacks versus for whites (208).

5. *Socioeconomic status*

Smokers who are nonprofessionals, less educated, or poorer are more likely to start smoking and, once they start, are less likely to stop (11, 209). Although not well studied, smokers of low socioeconomic status probably have less social support for cessation and may have less knowledge of the harm from smoking and the benefits of cessation (209). Finally, these smokers have less access to formal therapies for smoking cessation (209). One study of providing free smoking cessation therapy (i.e., nicotine replacement therapy) to low-income smokers found quit rates similar to those of higher socioeconomic groups (210). There are no replicable results to indicate how to modify treatment for smokers of low socioeconomic status.

D. TYPE OF TOBACCO

1. *Cigarettes*

The data and conclusions cited in the previous sections are for treatment of cigarette smoking. Cigarettes comprise over 95% of tobacco consumption in the United States (11). Cigarettes are very dependence producing because the inhalation route produces high arterial concentrations of nicotine that very quickly reach the brain (15, 42). In addition, the cigarette is a delivery device that allows easy titration of the dose to achieve different effects (15, 42). Finally, the high availability of cigarettes and multiple cues for their use make cessation difficult (15, 42).

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2. *Smokeless tobacco*

The prevalence of smokeless tobacco use has increased dramatically in the last decade (211). Most users are young men (212). Smokeless tobacco provides nicotine via buccal absorption (211, 212), with a slower rate of nicotine absorption but resultant nicotine blood levels similar in magnitude to those produced by cigarettes (42, 213). Smokeless tobacco use can induce nicotine dependence, including a withdrawal syndrome (42, 213). Smokeless tobacco use produces medical harm including gingivitis, oral cancers, etc. (211–213). Often, smokeless tobacco users have detectable and readily observable oral lesions that can be used as motivators (211).

Although the cessation rates with behavior therapy are somewhat low in smokeless tobacco users, behavioral therapy appears effective and is recommended [II] (5, 211, 213). The single study of nicotine gum showed no efficacy (214). The efficacy of the nicotine patch, nonnicotine mint snuff, or other pharmacotherapies for cessation of smokeless tobacco have not been tested. Nevertheless, given that smokeless tobacco users appear nicotine dependent, a trial of nicotine patch therapy is indicated in those who have failed because of withdrawal symptoms [III].

3. *Patients who smoke pipes/cigars*

The major distinction among pipe and cigar smokers is whether they are primary or secondary (i.e., previously used cigarettes) users, as secondary pipe/cigar users smoke more intensely (213) and thus may be more nicotine dependent. Although nicotine dependence is likely to occur in some pipe and cigar users, there is no empirical data on nicotine dependence or its treatment in this group. However, based on the data from adults, pipe and cigar smokers who are nicotine dependent should benefit from the same treatments recommended for cigarette smokers [III].

VI. RESEARCH DIRECTIONS

Several reviews have outlined research directions for developing treatments for smokers without concomitant psychiatric disorders (60, 66, 101, 213, 215–217); thus, the following section will focus only on research directions for the psychiatric aspects of smoking.

A. EPIDEMIOLOGY AND NATURAL HISTORY OF NICOTINE DEPENDENCE

Nicotine dependence per se has been studied much less than has alcohol or other drug dependencies. To our knowledge there are only two population-based studies of the prevalence and correlates of nicotine dependence using the DSM-IV criteria (32, 218) and only one using the Fagerstrom scale (219). Serial cross-sectional and longitudinal epidemiological studies of nicotine dependence are needed to determine a) whether the prevalence of nicotine dependence among smokers is increasing over time, b) whether certain groups (e.g., the poor, those with nonnicotine drug dependencies, those with a history of depression) are especially vulnerable to developing nicotine dependence if they take up smoking, and c) the natural history of nicotine dependence (e.g., how soon does it develop, whether some smokers are immune to developing dependence).

B. EPIDEMIOLOGY AND NATURAL HISTORY OF SMOKING IN PSYCHIATRIC PATIENTS

Although the natural history of smoking initiation and cessation is quite well described, similar studies in psychiatric patients are almost completely absent. Studies of the prevalence and incidence of initiation and cessation of smoking, movement through the stages of change, rates of quit attempts, relapse rates, etc., are needed for smokers with major psychiatric disorders.

C. MORBIDITY FROM SMOKING IN PSYCHIATRIC PATIENTS

How often psychiatric patients die from smoking-related diseases is not known. Demonstration that many psychiatric patients die from smoking-related illnesses might help motivate psychiatrists to be more aggressive in their treatment of nicotine dependence. Prior case-control mortality studies of psychiatric disorders have often not factored in the much higher rates of smoking in psychiatric patients; e.g., the high rates of cancer in depressed patients may be more related to their smoking habits than the competence of their immune system.

D. PATIENT-TREATMENT MATCHING

As indicated previously, there are a few empirically based studies of treatment-matching strategies for smokers with different levels of motivation to quit (39, 70), for different types of behavior therapy (102, 103), and for the use of nicotine gum (12) or nasal spray (147) in highly versus less-nicotine-dependent patients. At present there are contradictory data on how to determine which patients need nicotine replacement (101). We are unaware of any data on how to select patients that especially need

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behavior therapy. Most importantly for this guideline, there are no data on how smokers with alcohol/drug abuse, anxiety, depression, or other psychiatric disorders should be matched to specific treatments.

E. TREATMENT OF SMOKING IN PATIENTS WITH A CURRENT PSYCHIATRIC DISORDER

One study has shown that behavioral/cognitive therapy for depression is especially helpful with smokers with mild depressive symptoms (180, 195). Other studies have tested treatments for smoking among those with alcohol and other drug dependencies, but none have had much success (34). As described earlier, smokers with nonnicotine psychiatric drug disorders appear to have more difficulty stopping smoking (2, 167); thus, studies of efficacy of treatments of different content and duration in smokers with past or present histories of specific psychiatric disorders, especially depression and schizophrenia, are needed.

F. TREATMENT OF WITHDRAWAL ON SMOKE-FREE UNITS

As described earlier, several studies have found that smoke-free units are not as difficult to manage as predicted (190). However, because smoking cessation causes nicotine withdrawal symptoms that overlap with many psychiatric symptoms (e.g., irritability, insomnia), cessation has been hypothesized to interfere with psychiatric diagnosis, to worsen several psychiatric disorders, to cause relapse in some patients in remission, to mimic or worsen side effects from several medications, and to substantially increase blood levels of several medications (2, 8). Whether these effects are clinically significant needs to be studied.

VII. INDIVIDUALS AND ORGANIZATIONS THAT SUBMITTED COMMENTS

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American Academy of Pediatrics
American Association of Suicidology
American College of Cardiology
American College of Preventive Medicine
American Medical Association
American Psychoanalytic Association
American Society of Addiction Medicine
Association for Advancement of Behavior Therapy
Center for Substance Abuse Prevention
Center for Tobacco Research and Intervention
The Cochrane Collaboration
The Menninger Foundation
National Association of VA Chiefs of Psychiatry
National Cancer Institute
National Institute on Drug Abuse
National Institute of Health
National Institute of Mental Health
Pakistan Psychiatric Society of North America
Royal College of Psychiatrists
Society for Adolescent Medicine
Western Psychiatric Institute and Clinic

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VIII. REFERENCES

The following coding system is used to indicate the nature of the supporting evidence in the summary recommendations and references:

[A] Randomized clinical trial. A study of an intervention in which subjects are prospectively followed over time; subjects are randomly assigned to treatment and control groups; both the subjects and the investigators are blind to the assignments, except psychosocial treatments may not be double-blind.

[B] Clinical trial. A prospective study in which an intervention is made and the results of that intervention are tracked longitudinally; study does not meet standards for a randomized clinical trial.

[C] Cohort or longitudinal study. A study in which subjects are prospectively followed over time without any specific intervention.

[D] Case-control study. A study in which a group of patients is identified in the present and information about them is pursued retrospectively or backward in time and compared to matched control subjects.

[E] Review with secondary data analysis. A structured analytic review of existing data; e.g., a meta-analysis or a decision analysis.

[F] Review. A qualitative review and discussion of previously published literature without a quantitative synthesis of the data.

[G] Other. Textbooks, expert opinion, case reports, and other reports not included above.

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EXHIBIT
4

PHILIP MORRIS

U.S.A.

120 PARK AVENUE, NEW YORK, N.Y. 10017-5592 TELEPHONE (212) 880-5000

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Dear Fellow Employee:

Drug abuse continues to present a serious problem for our society, including today's business world. Individuals who use drugs can be a threat to themselves and to others in the workplace.

Philip Morris U.S.A. strives to ensure safe and healthful working conditions for all our employees. In keeping with this effort, we have always prohibited drug use and related acts, such as giving or selling drugs, in the workplace.

Our Drug Abuse Policy has recently been updated, and contains some important changes. The updated policy is included in the brochure accompanying this letter. In addition, the brochure contains information on different types of drugs, their effects, and their dangers. Information on sources of help with drug problems is included as well.

Please take the time to review the contents of this brochure carefully. All employees are responsible for understanding and adhering fully to the Drug Abuse Policy.

Philip Morris U.S.A. continues to stand by its commitment to maintain a safe workplace. We are confident that our updated Drug Abuse Policy, and educational efforts such as this brochure, will contribute to the maintenance of a safe and healthful work environment.

Mike Szymanczyk
Senior Vice President, Sales

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Creating Competitive Advantage

Develop a People Advantage

Drug Free Workplace Act: Policy Guidelines

prepared by RJRTO in HUMPHREY

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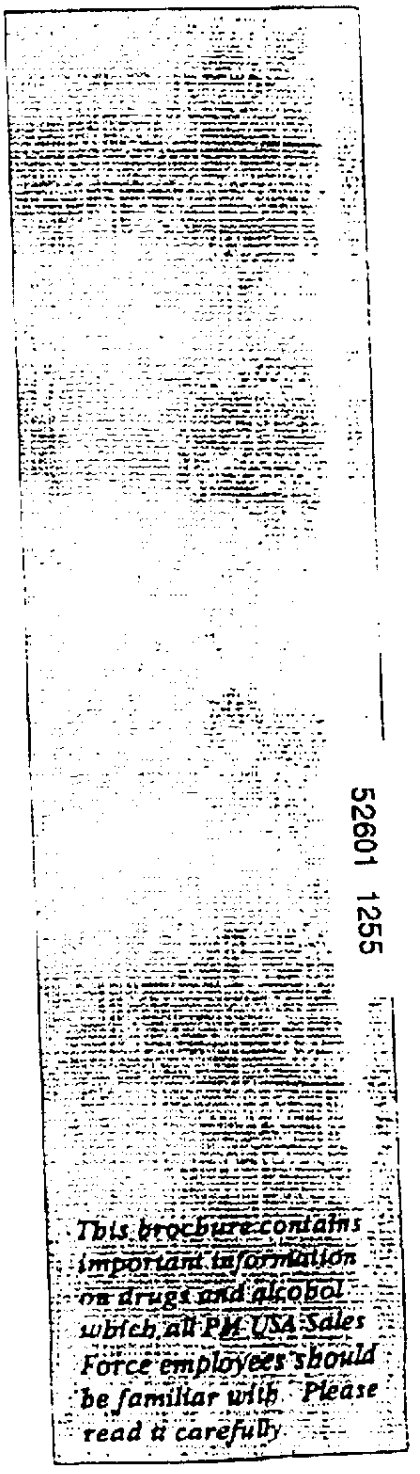

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This brochure contains important information on drugs and alcohol which all PM USA Sales Force employees should be familiar with. Please read it carefully.

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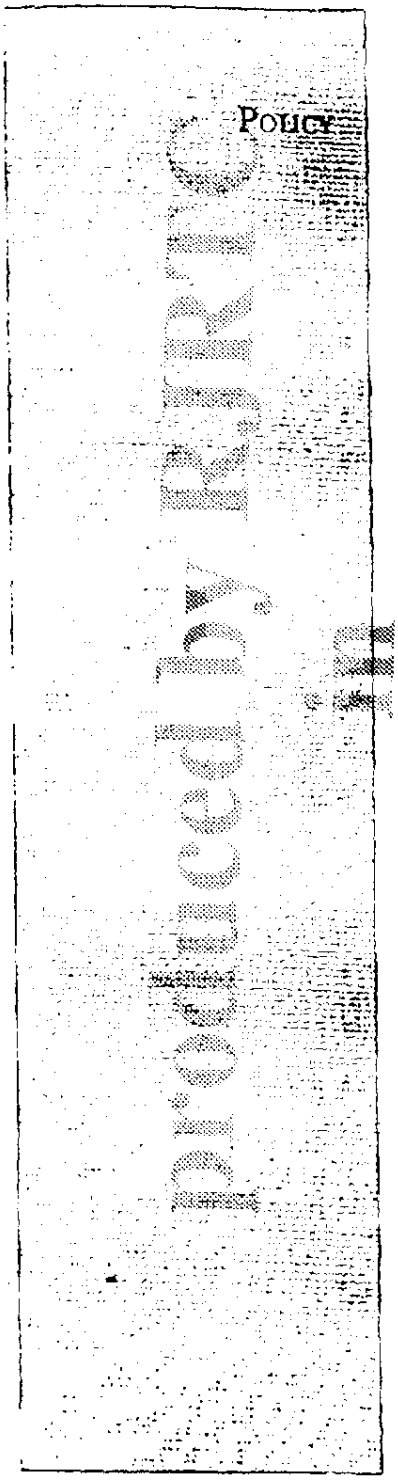

I. Drug Abuse Policy – Revised August 1992

It is the established policy of Philip Morris U.S.A. to provide a safe, drug-free working environment for its employees. In addition, the Company complies with all provisions of the Drug-Free Workplace Act of 1988.

All employees are expected to be present at work as scheduled; to be in suitable mental, emotional, and physical condition when at work; to perform their jobs satisfactorily; and to behave appropriately. When the use of drugs interferes with such expectations or in any other way has an adverse effect on the Company, employees have the opportunity to obtain appropriate assistance on a confidential basis through the Company-sponsored Employee Assistance Program or a program approved by the Company's Benefits Department.

Failure of employees to meet the basic expectations described above and/or to avail themselves of the proffered assistance prior to violating the Company Drug Abuse policy will result in disciplinary action up to and including termination. In other words, participation in the Employee Assistance Program or another approved rehabilitation program is not a shield against discipline; such participation does not supersede the Company Drug Abuse policy or any discipline for violation of its provisions.

Covered in this policy is the use of all forms of narcotics, depressants, stimulants, and hallucinogens, including marijuana and cocaine.

The sale, purchase, transfer, use, or possession of illegal drugs or unauthorized prescription drugs on Company property including vehicles, etc., will result in disciplinary action, up to and including termination. The use of drugs, other than for prescribed medical reasons, during working hours or while in a representational capacity for the Company, whether on or off Company property or inside or outside of vehicles, is prohibited.

In general, medically-prescribed drugs used in conformance with appropriate medical instructions are exempt from this policy. However, the Company reserves the right to evaluate such situations and to determine whether legal drugs taken under medical supervision impact an individual's ability to perform all aspects of the employee's job satisfactorily and safely.

Employees are encouraged to advise their supervisors whenever they are taking drugs for medical reasons that may affect their behavior or job performance. Whenever use of prescribed drugs has an adverse reaction which negatively affects job performance and/or safety, the employee should be relieved of his or her duties for the duration of the impairment.

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A. Applications

Pre-Employment Drug Screening

All prospective Sales Force Employees are required to successfully complete a pre-employment drug screen prior to being accepted for employment with Philip Morris U.S.A.

Applicants

Applicants for employment will be advised of the Company's position with regard to this policy and compliance with the federal Drug-Free Workplace Act of 1988.

Employee Assistance Program

Philip Morris will give the same consideration to employees with drug dependency problems as it does to employees having other health problems. Actively seeking assistance and cooperating with a prescribed treatment regimen will not place an employee's job at risk; however, violations of the Company's Drug Abuse policy prior to seeking rehabilitation and assistance, unsatisfactory performance, attendance, punctuality, or behavioral problems may place the employee's job in jeopardy, even if the prescribed treatment is followed.

Philip Morris provides an Employee Assistance Program, a confidential referral for counseling and/or treatment programs, as a part of its Benefits Plans. Information about the Employee Assistance Program is provided in the Employee Handbook, and is available from the Human Resources – Sales department.

Employees who are experiencing problems with drugs are strongly encouraged to make use of the Employee Assistance Program in order to avoid violating the Company Drug Abuse policy. Employee participation in the program and adherence to the prescribed rehabilitation program will be given serious consideration in any employment decision involving drug use, but such participation does not exempt the employee from discipline, and it does not supersede the Company's right to discipline an employee for violations of the policy.

PROCEDURES

Refer to Section III of this brochure for more information about other sources of assistance for drug- and alcohol-related problems.

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While we hope PM USA will never have to discuss drug problems with any employee, it is only fair that every member of the Sales Force understand the consequences of violating this policy.

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Violation of Company Rules

Whenever there is reasonable cause to believe that an employee has violated the Company's policy (as characterized, for instance, by aberrant or erratic behavior on the job), that employee will be subject to immediate suspension, with pay, pending a Company investigation.

Note: In the course of a Company investigation, employees suspected of violating this policy may be required to submit to a Fitness for Work examination, which may include a screening drug test(s). Employees will be advised that such tests may be administered.

If the results of the test(s) confirm a positive drug finding, such results will be communicated to the employee's Supervising Manager and the Director, Employee Relations - Sales. While an employee may decline to be tested, such a declination constitutes grounds for disciplinary action up to and including termination.

If, after the investigation is completed, the employee is found not to have violated this policy, the employee will be returned to work.

If, after investigation, the Company determines that the employee has violated this policy, corrective action will be taken against the offending employee, which will involve disciplinary action up to and including termination. The course of action to be taken will be determined jointly by Sales Management and the Human Resources - Sales department.

Note: If an employee is charged with a workplace-related criminal offense due to possession and/or use of controlled substances, the individual will be placed on a Special Authorized Leave of Absence. Reinstatement will be considered based on a number of factors, including the Company's internal investigation and the outcome of the legal proceedings. This is in accordance with Philip Morris' Policy concerning reasons for Special Authorized Leave of Absence.

Additionally, an employee involved in an accident while operating a Company vehicle will be required to undergo a drug screen, in accordance with the procedures specified in the Vehicle Safety Policy.

PRELIMINARY

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B. Responsibilities

Employees

As required by the Drug-Free Workplace Act, an employee **must** notify in writing his or her immediate supervisor and the Manager, Region Employee Relations **within 5 days** upon being convicted of **any criminal drug offense**. Failure to carry out these responsibilities will result in disciplinary action up to and including termination.

Supervising Manager

It is the responsibility of Sales Management to report workplace-related situations, as defined in the policy statement, where possession and/or use of illegal drugs may be taking place. When a member of Sales Management observes such use or possession of illegal drugs, it is his/her responsibility to:

Immediately notify the next level of field management up to and including the Vice President, Region Sales and the Manager, Region Employee Relations.

Take steps to document the event, including statements from any other individuals who observed the situation.

Manager, Region Employee Relations

Immediately inform the Director, Employee Relations – Sales of any violations or alleged violations of this policy.

Conduct investigations of violations of this policy with Sales Management and the Director, Employee Relations – Sales.

Director, Employee Relations – Sales

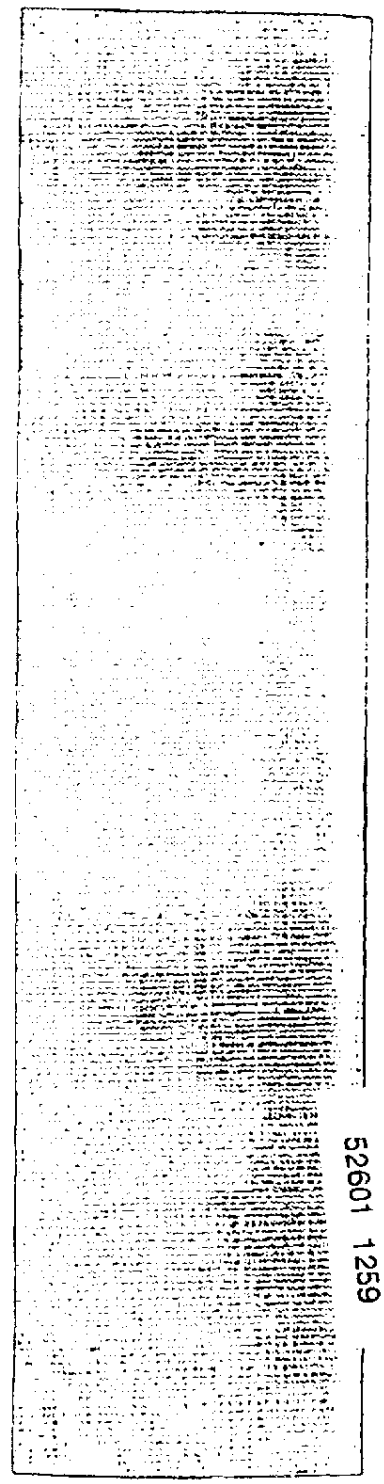
As required by the Drug-Free Workplace Act of 1988, ensure that:

The appropriate contracting agency or agencies is informed within 10 days after notification of an employee workplace-related criminal drug conviction.

Appropriate disciplinary action is taken against such employee(s) within 30 days of notification of such workplace-related criminal drug conviction, or, require satisfactory enrollment and participation in a drug rehabilitation program.

Interpretation of Policy

Direct questions to the Manager, Region Employee Relations. The Manager, Region Employee Relations will consult with the Director, Employee Relations-Sales, as the need arises.



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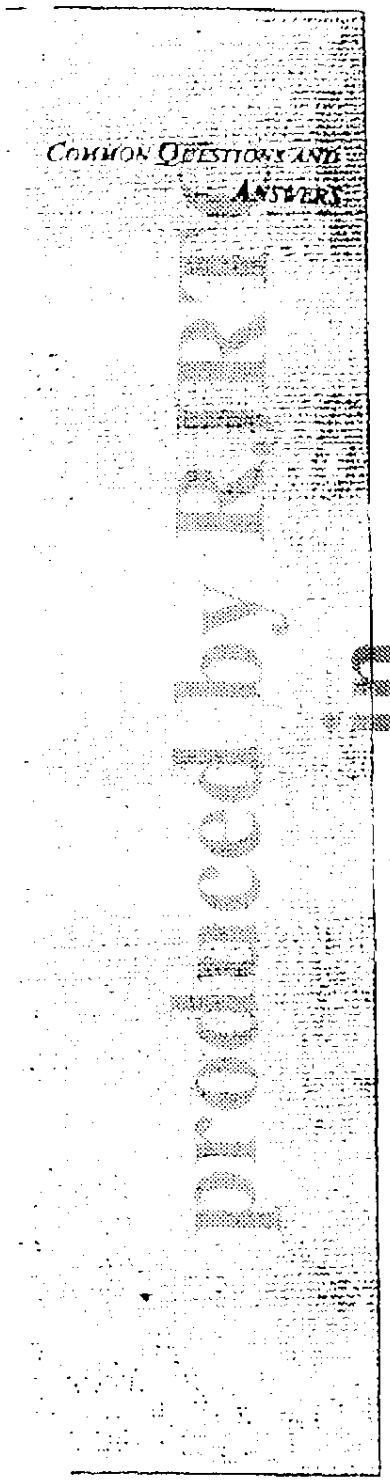

II. Drugs and their Effects

What is a drug?

A drug is any chemical substance, natural or synthetic, which produces physical, mental, emotional, or behavioral change in the user.

What is drug abuse?

Drug abuse is the use of a drug for other than medicinal purposes which results in the impaired physical, mental, emotional, or social well-being of the user.

Which drugs are abused?

Alcohol, barbiturates, narcotics, amphetamines, cocaine, crack, marijuana, and hallucinogens are among the most commonly abused drugs, although the list is endless. Drugs which can be legally prescribed for medicinal purposes can also be abused, through misuse or use by someone other than the person for whom the drug was prescribed.

What is drug addiction? Is there a difference between physical and psychological dependence?

Drug addiction is a term often used to describe a user's "physical" dependence on a drug. Physical drug dependence is characterized by physiological changes, in which the body becomes used to a drug and needs it to function. When the individual stops taking the drug, he or she will experience withdrawal symptoms, such as vomiting, tremors, sweating, insomnia, and possibly, convulsions. The term is gradually being replaced with the more generic term "drug dependence".

Drug dependence is the need for a drug which results from continuous or periodic use of that drug, and may include both physical and psychological dependence. Psychological dependence occurs when an individual feels a drug is needed in order to feel good, or normal, or just "get by". Psychological withdrawal is characterized by anxiety and cravings, both of which may be extremely intense.

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What is alcoholism? Who is an alcoholic?

Most experts agree that a person has a problem with alcohol, or is an alcoholic, if:

1) he or she cannot abstain (e.g., feels that he or she cannot get through the day, night, event, etc., without a drink),

OR

2) he or she cannot control his or her drinking (e.g., is unable to stop drinking after one or two drinks),

OR

3) his or her drinking has a negative impact on families, friends, and jobs.

Why do people abuse drugs?

There are many reasons. Some people wish or believe that drugs can help them "escape" from tensions, problems, and reality. Continuous social pressures and peer influences play a role. This is particularly true for young people, although it can influence all of us. In addition, many drugs can be obtained with relative ease.

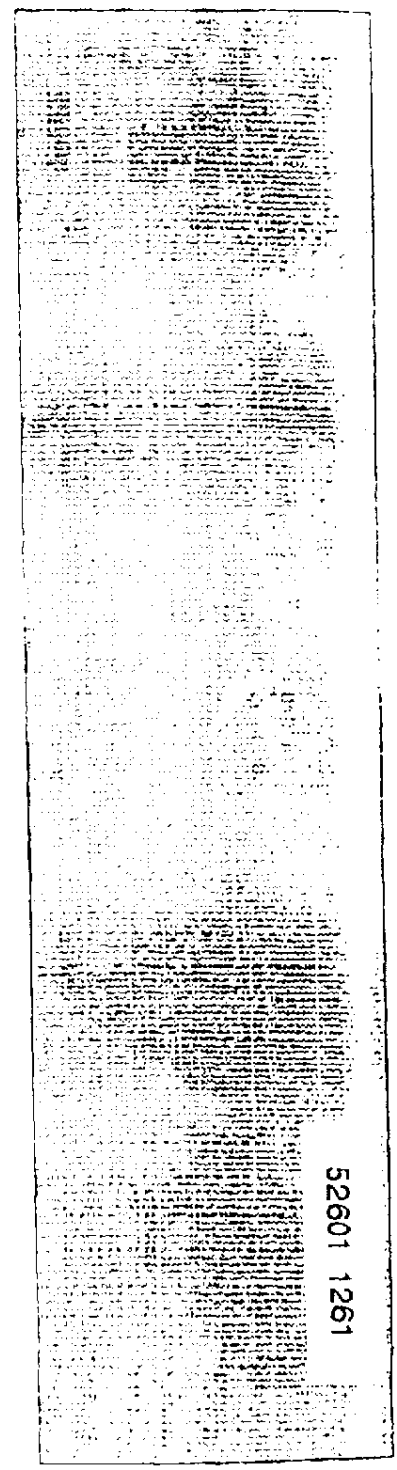
Continuous use of drugs leads to other, extremely powerful motivations to continue to use, notably those stemming from physical and/or psychological dependence.

Is it dangerous to use drugs during pregnancy?

It most certainly can be. Pregnant women should be extremely cautious about taking any drug, even aspirin, without first consulting their physician.

Is it possible to get medical help for drug problems without getting into legal trouble?

Yes. There are regulations which protect the confidentiality of patients in treatment. Doctors, psychologists, and drug treatment centers are required by Federal law to keep confidential any information obtained from patients. However, in certain circumstances the law does allow for disclosure, so that, for example, other doctors can treat the patient, or so that insurance providers can provide benefits. (It is best to discuss these issues with your health care provider.)



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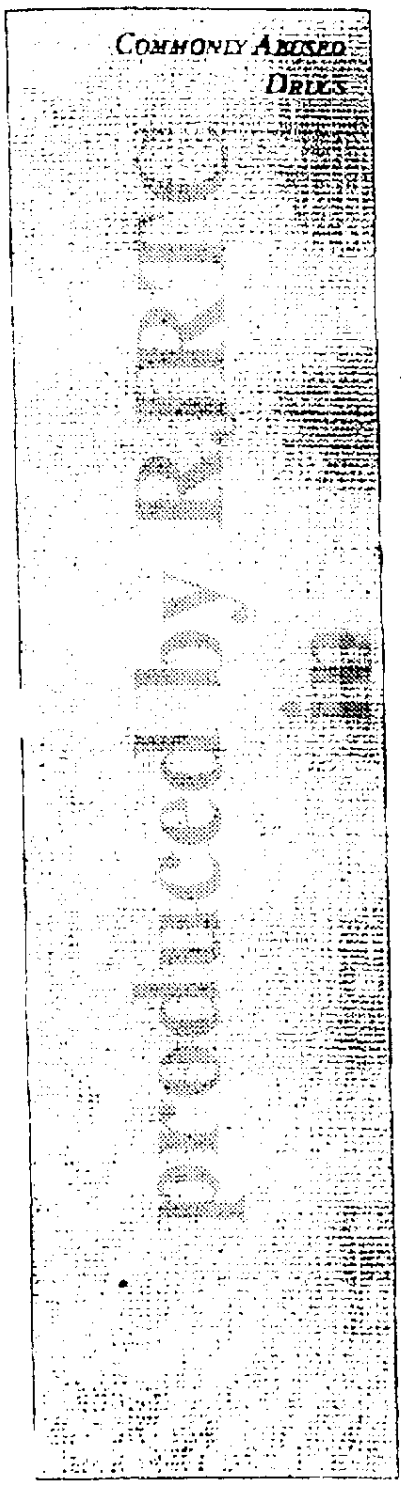

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DRUG: *Alcohol*

EFFECTS:

Initially, alcohol tranquilizes and relaxes some people. For others, alcohol appears to have a stimulating effect. Restraint is weakened and tension released, which may cause a carefree feeling.

Alcohol depresses activity in the central nervous system, and acts first to depress activity in those parts of the brain associated with self-control, decreasing inhibitions.

In larger amounts, alcohol can dull sensations and seriously impair memory and judgement. Voluntary motor actions, such as walking, and actions involving eye-hand coordination become seriously impaired.

In still larger amounts, deeper areas of the brain are affected, which may result in confusion, stupor, and loss of consciousness.

Ingested in large quantities over a long period of time, alcohol can damage the liver and heart, and can cause irreversible brain damage.

PSYCHOLOGICAL DEPENDENCE: Yes

PHYSICAL DEPENDENCE: Yes

ADVERSE/OVERDOSE REACTIONS:

"Black-outs" (loss of memory of events during intoxicated state), confusion, incoherence, stupor, comatose state. Death is possible due to severe depression of brain centers which control heartbeat and breathing. Used in combination with other depressants (e.g., the barbiturates), the effects are greatly intensified and the risk of adverse reaction increases tremendously (see Barbiturates section).

EFFECT ON DRIVERS:

Even one or two drinks can impair a driver's judgement and reaction time. Research shows that a driver who consumes between six and seven drinks in a two-hour period and then gets behind the wheel of a car is 100 times the traffic risk of a non-drinking driver. One half of the 50,000 deaths from car accidents each year in the United States are alcohol-related.

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USE BY PREGNANT WOMEN:

Recent studies show that pregnant women who drink heavily (defined as drinking more than three ounces of alcohol a day, the equivalent of about two mixed drinks, or two twelve-ounce beers, or two five-ounce glasses of wine) run a higher risk than other women of having babies with physical, mental, and behavioral abnormalities.

"Fetal Alcohol Syndrome" can be the result of heavier alcohol abuse during pregnancy, and is characterized by mental retardation and physical deformities in the child.

Some studies have demonstrated that lighter drinking, or an occasional "binge", can affect an unborn child, but the evidence is less clear-cut.

DRUG: *Barbiturates*

STREET NAME: Yellowjackets, yellows, reds, ludes, downers

EFFECTS:

Many barbiturates may be legally prescribed to induce sleep and reduce stress. Relaxation, sleepiness, slowed mental and physical functioning, and impulsiveness are common effects. Bizarre thoughts, disorientation, and slurred speech may occur with higher doses.

PSYCHOLOGICAL DEPENDENCE: Yes

PHYSICAL DEPENDENCE: Yes

ADVERSE/OVERDOSE REACTIONS:

Confusion, decreased response to pain, shallow respiration, weak and rapid pulse. Due to depression of central nervous system functioning, the centers controlling breathing and heartbeat in particular, coma and death are possible when ingested in larger amounts.

In combination with alcohol, may cause relaxation of the diaphragm to the degree that the user suffocates.

USE BY PREGNANT WOMEN:

Babies born to barbiturate-dependent mothers are often themselves born physically dependent, and require special care and treatment. These infants suffer painful and dangerous withdrawal symptoms after birth.

Barbiturates include Nembutal, Seconal, and Phenobarbital. Quaalude, a street drug, is closely related to the barbiturate family and has similar effects.

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Narcotics include the opiates, and drugs derived from opium, including heroin, morphine, and codeine. In the U.S., heroin accounts for 90% of all narcotics abuse. The term also includes synthetic drugs which have similar actions, such as methadone.

DRUG: *Narcotics*

METHOD OF CONSUMPTION: Injection, inhalation, ingestion

EFFECTS:

Narcotics reduce physical pain and cause drowsiness. Euphoria, relaxation, apathy, difficulty in concentrating, slowed speech, decreased physical activity, drooling, itching, and nausea have all been reported.

Morphine, a very powerful pain suppressant and sleep inducer, is legally available, as is codeine, an ingredient in many prescription pain and cough suppressants.

Methadone is a synthetic narcotic used in the treatment of heroin dependence. It reduces the craving for heroin and prevents the onset of withdrawal symptoms, without producing the "high" that accompanies heroin use. (Heroin withdrawal begins within four to six hours after a heroin dependent person's last injection. Shaking, sweating, vomiting, chills, abdominal pains, and diarrhea, all typical withdrawal symptoms, appear within 12-16 hours.)

Methadone also causes physical dependence. However, in treatment centers, it can be carefully regulated and administered. Many treatment centers provide for methadone withdrawal, once heroin dependence has been successfully treated.

PSYCHOLOGICAL DEPENDENCE: Yes

PHYSICAL DEPENDENCE: Yes

ADVERSE/OVERDOSE REACTIONS:

Depressed levels of consciousness, low blood pressure, rapid heart rate, shallow breathing, convulsions, coma, and death are possible.

Physical dangers depend on the specific drug and dosage level, its source, and the way it is used. Unsterile needles, syringes, and other paraphernalia can cause any of several diseases (e.g., serum hepatitis is common). The life expectancy of the intravenous heroin user is significantly shorter than that of one who "snorts" or ingests the drug.

Actual heroin concentration can vary widely from purchase to purchase. If the amount of heroin is much higher than the user is accustomed to, the overdose can result in death. Contamination or combinations of heroin with other substances or drugs can be lethal when injected intravenously.

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DRUG: *Cocaine*

METHOD OF CONSUMPTION: Inhalation, injection, ingestion. Also smoked in a form called "freebase". Freebase is the most toxic form of cocaine. Smoking freebase is the fastest way to get the drug to the brain and therefore offers the quickest "high".

STREET NAME: Coke, blow, snow, toot

EFFECTS:

Increased confidence and pleasant sense of power, mood elevation, sense of energy and alertness have been reported. Decreased appetite and weight loss, anxiety, restlessness, irritability, suspiciousness, and insomnia have been reported as well, among regular users.

PSYCHOLOGICAL DEPENDENCE: Yes

PHYSICAL DEPENDENCE: No clear evidence

ADVERSE/OVERDOSE REACTIONS:

Paranoia not uncommon. After a period of regular use, depression may occur upon cessation which may be severe, causing users to return to the drug. Bizarre behavior has also been reported, as well as hallucinations of touch, sight, taste, and smell. Heavy, repeated doses may trigger psychosis in users who are prone to mental instability.

Repeated inhalation often results in irritation of the nostril and nasal membranes. Injection with non-sterile equipment can cause hepatitis or other infection.

Cocaine is toxic. Although rare, cocaine overdose deaths have occurred from injection, inhalation, and ingestion of the drug, typically as a result of seizures followed by respiratory or cardiac arrest.

Freebase users appear to form the strongest psychological dependencies of all cocaine users, and appear less able or willing to control their use of the drug.

DRUG: *Crack*

METHOD OF CONSUMPTION: Smoked.

Cocaine is a stimulant which increases the rate of activity in the central nervous system.

Crack is smokable cocaine, also known as "rock" cocaine. Widely considered the most addictive illegal drug now on the market.

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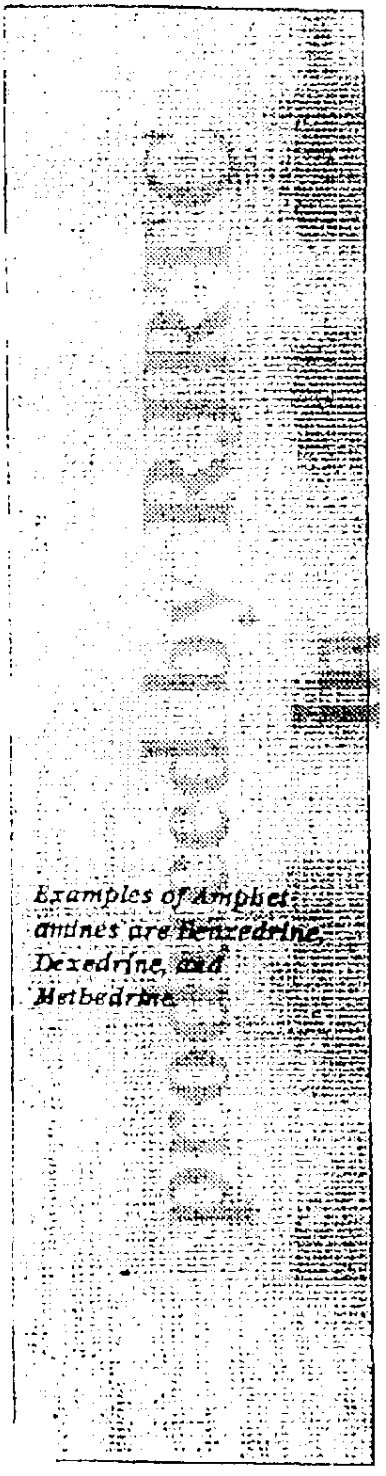

Examples of Amphetamines are Benzedrine, Dexedrine, and Methedrine.

EFFECTS:

Reaches the brain in less than ten seconds. Euphoria (markedly greater than that produced by other forms of cocaine), hyperactivity, unpredictability, followed within minutes by feelings of depression, which may be quite pronounced. A crack "high" lasts between 5 and 20 minutes.

PSYCHOLOGICAL DEPENDENCE: Yes, which may be extremely pronounced and may develop within two weeks of using the drug.

PHYSICAL DEPENDENCE: No clear evidence

ADVERSE/OVERDOSE REACTIONS:

Intensely addictive. Also, crack is deceptively affordable, as it is typically sold in $10.00 increments (for one crack pellet). As dependency progresses and usage increases, the cost of the habit increases geometrically.

USE BY PREGNANT WOMEN:

Studies have documented birth defects in infants whose mothers used crack during pregnancy.

DRUG: *Amphetamines*

STREET NAME: Speed, uppers

EFFECTS:

Feeling of confidence and alertness. Mood elevation, increase in speech and general physical activity, decreased appetite, anxiety, irritability, insomnia.

There are a few medical uses of amphetamines, including controlling appetite on a short-term basis, treating children with minimal brain damage, and treating narcolepsy, a rare disorder characterized by immediate and uncontrollable need for sleep.

PSYCHOLOGICAL DEPENDENCE: Only for heavy users

PHYSICAL DEPENDENCE: No clear evidence, physiological depression may occur upon withdrawal.

UNDER SEAL

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ADVERSE/OVERDOSE REACTIONS:

Paranoia and feelings of persecution, mood swings, panic, circulatory and cardiac disturbances, hallucinations, convulsions, and coma have all been reported.

Heavy, frequent doses may produce brain damage resulting in speech disturbances, such as difficulty in translating thoughts into words. Death can occur with amphetamine overdose.

If injected and used heavily, toxins may build up in the user's body, resulting in a condition known as amphetamine psychosis. Amphetamine psychosis is characterized by extreme suspiciousness, bizarre, and sometimes violent behavior.

DRUG: *Marijuana*

METHOD OF CONSUMPTION: Smoked, or less commonly, ingested.

STREET NAME: Dope, pot, grass, smoke, weed

EFFECTS:

Feelings of euphoria, relaxation, and bouts of exaggerated laughter are commonly reported. Many feel that their hearing, vision, and skin sensitivity are enhanced by the drug. Increase in heart rate, dryness of the mouth and throat, and reddening of the eyes often accompany marijuana usage.

PSYCHOLOGICAL DEPENDENCE: Yes

PHYSICAL DEPENDENCE: No clear evidence

ADVERSE/OVERDOSE REACTIONS:

Although rare, feeling of panic, anxiety, and paranoia have been reported.

Regular, long-term (6 months or more) marijuana use may reduce fertility in women. Studies show that such users are three times more likely to have defective menstrual cycles, characterized by failure to ovulate or a shortened period of fertility. Chronic male marijuana users have lower levels of testosterone than nonusers. Upon stopping drug use, testosterone levels return to normal. Research also indicates that sperm count diminishes as level of marijuana use increases. In addition, some of the sperm of chronic users are defective and non-functional.

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ADVERSE/OVERDOSE REACTIONS:

Paranoia and feelings of persecution, mood swings, panic, circulatory and cardiac disturbances, hallucinations, convulsions, and coma have all been reported.

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PHYSICAL DEPENDENCE: No clear evidence

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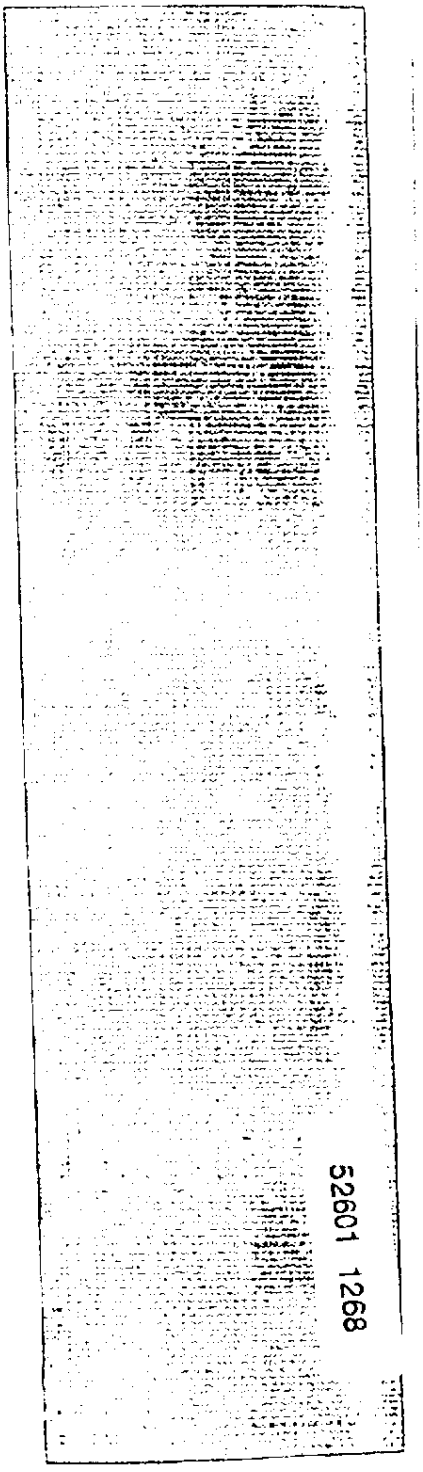

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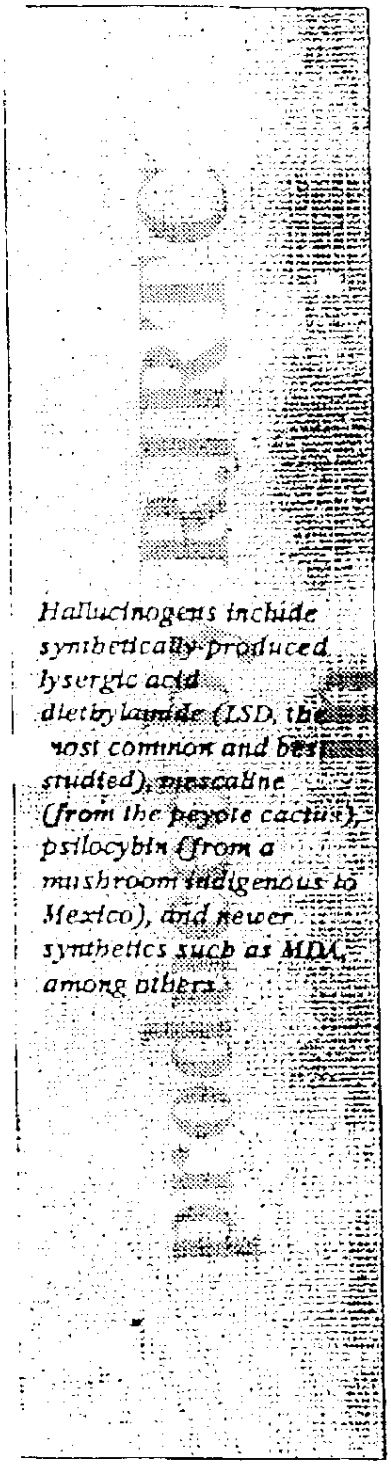

Hallucinogens include synthetically produced lysergic acid diethylamide (LSD, the most common and best studied), mescaline (from the peyote cactus), psilocybin (from a mushroom indigenous to Mexico), and newer synthetics such as MDA, among others.

EFFECTS ON DRIVERS:

Actual driving experiments reveal that the drug has a significant impact on judgement, caution, and concentration. Other studies indicate that marijuana effects perceptual and motor skills, abilities used when operating a motor vehicle, as well.

USE BY PREGNANT WOMEN:

Research is limited because of possible risks to the unborn child. However, marijuana can cross the placental barrier and thus can reach the fetus. Some scientists believe that using marijuana during pregnancy may have a toxic effect on embryos and fetuses. Almost all physicians and psychologists agree that using marijuana during pregnancy is an unnecessary risk.

DRUG: *Hallucinogens (also known as psychedelics)*

EFFECTS:

These drugs are capable of producing changes in perception.

Vivid visual and auditory hallucinations are reported. Users report fascination with ordinary objects, and heightened esthetic responses to color, texture, spatial arrangements, and music.

Slowing of time and magnified feelings of love, hate, joy, pain, terror, despair, etc. are also common. Paranoia, euphoria, and feelings of panic are reported as well.

Some individuals claim heightened creativity accompanies use of the drug, but research fails to support this assertion.

PSYCHOLOGICAL DEPENDENCE: Only for a minority of users

PHYSICAL DEPENDENCE: No

ADVERSE/OVERDOSE REACTIONS:

Some individuals report being terrified by the experience, especially if the user has experienced emotional difficulties in the past.

Nausea and chills, increased pulse, temperature, and blood pressure, and trembling are possible. Loss of appetite and insomnia are commonly reported.

Some individuals under the influence of LSD have displayed bizarre and dangerous behavior which has led to injury or death.

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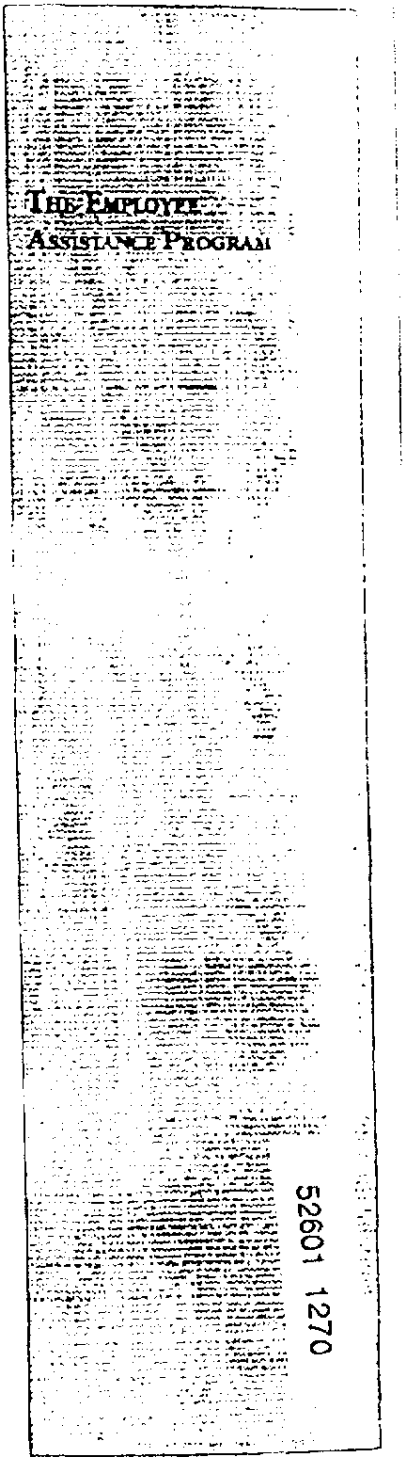
Stanford Research Into the Impact of Tobacco Advertising http://www.industrydocuments.ucsf.edu/docs/zkxl0001

III. Sources of Help for Drug and Alcohol Problems



Philip Morris provides an Employee Assistance Program (EAP) as a part of its Benefits Plans. The EAP is a referral service for counselling and/or treatment programs. The types of services provided by the EAP are numerous, and include assistance with drug and alcohol abuse and related problems, and with many other personal problems as well.

The EAP provides **free, independent, and confidential** referral services for Sales Force employees and their families.

No one in the Company will know if, when, or why you call the EAP.

Additional information about the EAP is available from the Human Resources – Sales department.

NATIONAL RESOURCES

Information, Referrals, Hotlines, and Support Groups

Alcoholics Anonymous World Services
P.O. Box 459 Grand Central Station
New York, New York 10163
(212) 686-1100

Cocaine Anonymous
1-800-347-8998 toll-free

Narcotics Anonymous
P.O. Box 9999
Van Nuys, California 91409
(818) 780-3951

National Council on Alcoholism and Drug Dependency
1-800-NCA-CALL toll-free

National Institute on Drug Abuse Hotline
1-800-662-HELP toll-free

American Council on Alcoholism Helpline
1-800-527-5344 toll-free

800 Cocaine - An Information and Referral Hotline
1-800-COCAINE toll-free

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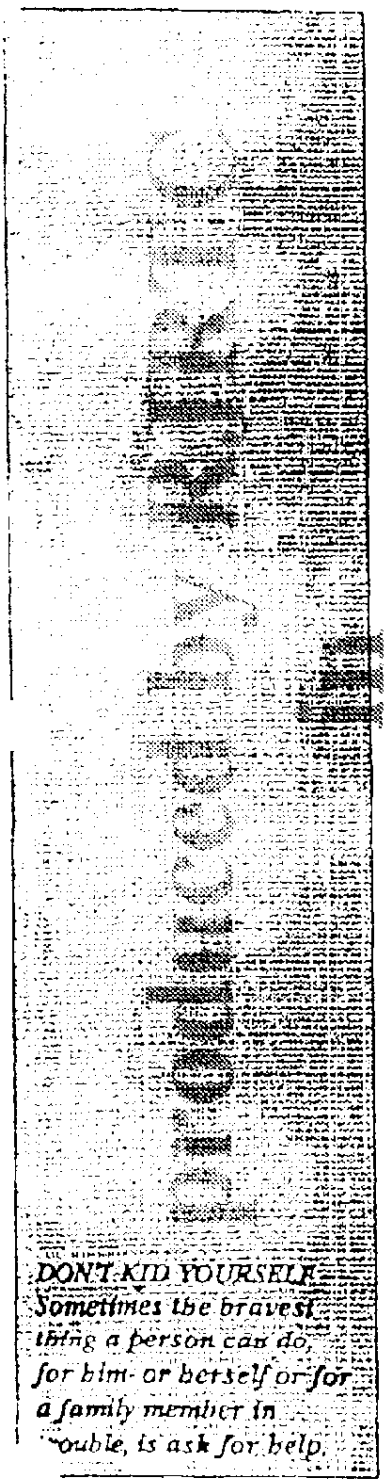

COMMUNITY RESOURCES

There are a variety of resources in your community which can also help with drug or alcohol problems. The best place to start is your local telephone directory under headings such as Alcohol/Drug Abuse Information, Treatment, or Counselling. Most of the National programs listed on the previous page also have local chapters.

Other support groups and services which can help you include local hospitals with outpatient treatment facilities, clergy, or church groups.

FAMILY AND FRIENDS

Support for Family and Friends of Drug or Alcohol Abusers

Al-Anon/Alateen Family Group Headquarters
P.O. Box 862
Midtown Station
New York, New York 11018
1-800-356-9996 toll-free

Nar-Anon Family Group Headquarters
P.O. Box 2562
Palos Verdes Peninsula, California 90274-0119
(213) 547-5800

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EXHIBIT

5

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Produced by R.J. REYNOLDS TOBACCO COMPANY

September 3, 1997

VIA HAND DELIVERY

SEP - 5 1997

Robert LaRocca, Esquire
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525 South 4th Street
Suite 5484
Philadelphia, PA 19147

Re: Arch v. The Tobacco Institute, et al.

Dear Bob:

Enclosed please find a copy of Dr. Michals' general report as well as his report as to the individual plaintiffs.

Very truly yours,

Howard M. Klein

HMK/gbm
Enclosures
cc: All Counsel on Attached Service List (via first-class mail)

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Philadelphia, PA 19102-2678

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TIMOTHY J. MICHALS, M.D.

Dr. Michals, whose curriculum vitae has already been produced, will testify concerning plaintiffs contention that they are each "addicted" to cigarette smoking. He will also testify as to the nature and definition of "addiction," the nature of cigarette smoking, and smoking maintenance and cessation. It is expected that Dr. Michals will testify that cigarette smoking fails to meet any classical scientific definition of addiction, and that cigarette smoking cannot reasonably be equated to addictions to drugs of abuse such as cocaine, heroin or amphetamines or alcohol. Dr. Michals is expected to testify that traditionally a substance is considered addictive only if it causes (a) intoxication, manifested by impaired judgment and cognition; (b) interference with social and occupational responsibilities (c) physical dependence, manifested by a consistently reproducible withdrawal syndrome; and (d) tolerance. Neither cigarette smoking, tobacco, nor nicotine can be classified as "addicting" or dependence producing under these criteria since: (a) they do not cause intoxication or impairment of judgment or cognition; (b) in his experience smokers, even heavy smokers, meet their social and occupational responsibilities without difficulty; (c) abstinence produces either no withdrawal syndrome or at most mild anxiety, and (d) individuals continue to smoke the same number of cigarettes for many years.

Dr. Michals is also expected to testify that cigarette smoking is a voluntary activity, which is best characterized as a ritual. It is a complex biological, psychological and social practice and that people smoke for many different reasons. Decisions regarding smoking and stopping smoking are personal decisions based on many factors, including personality, education, life experience, belief system, risk aversions, cultural background and other value system elements. It is Dr. Michals' opinion that there is nothing inherent about smoking that prevents a person from understanding and assessing the risks and benefits of smoking, making a

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decision to quit smoking, and/or carrying out that decision. Dr. Michals is also expected to testify to his opinion that motivation and commitment not to smoke is key in successfully stopping cigarette smoking, and that professional assistance is not necessary to stop smoking.

Dr. Michals is further expected to testify that no definition of "nicotine dependence" predicts anything about any individual's ability to quit smoking; that smokers quit smoking all the time; that as of 1993, there were about 46 million smokers and 46 million ex-smokers in the U.S.; that the vast majority of these people quit on their own, without smoking cessation aids; and that there are millions of smokers who do not wish to quit and who have simply not made a decision to stop smoking.

Dr. Michals may testify as to the opinions expressed by other witnesses in this case and the evidence upon which they rely, to the extent such evidence and opinions are within his area of expertise.

Dr. Michals will base his testimony on (1) his skill, education, training, and clinical experience as a psychiatrist; (2) his examination and psychological testing of the plaintiffs; (3) his knowledge of the scientific literature relating to smoking behavior and to "addiction" and substance dependence; (4) his review of the plaintiffs' medical records, depositions and depositions of their family members; and (5) the testimony of the expert witnesses in this action and additional testimony and documents as he deems necessary.

Dr. Michals' reports as to the individual plaintiffs are attached hereto.

Timothy J. Michals, M.D.

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Produced by R.J. Reynolds Tobacco Company in Response to Litigation

September 3, 1997

Howard M. Klein, Esquire
Conrad, O'Brien, Gellman & Rohn, P.C.
1515 Market Street, 16th Floor
Philadelphia, PA 19102-1916

RE: Edward Slivak
Barnes et al v. The American Tobacco Company et al

Dear Mr. Klein:

At your request and pursuant to the court order, I have conducted a psychiatric evaluation of Mr. Edward Slivak concerning this litigation. I conducted a clinical evaluation of Mr. Slivak in my office on August 12, 1997. Prior to my examination, I informed him that I was a psychiatrist and had been asked by your office to evaluate him concerning this litigation, that I would not be treating him and that what we discussed was not confidential since I would be sending a report of my evaluation to your office and could be called to testify in this litigation. He understood the purpose of the examination and gave his consent to be examined. My examination has consisted of a clinical evaluation conducted on August 12, 1997, psychological testing utilizing the Minnesota Multiphasic Personality Inventory-2 (MMPI-2), and my review of the following records and reports:

1. Cross & Moss, M.D. records;
2. Allegheny University Hospital - Hahnemann (Adm 05/06/93, 01/25/93);
3. Northeast Catholic High School;
4. Northeast Medical Surgical Associates;
5. Montgomery Hospital Business Office;
6. Philadelphia City of Police Personnel Office;
7. Independence Blue cross;
8. J.F.K. Memorial Hospital (Adm 07/03/89);
9. J.F.K. Memorial Hospital (ER Visit 03/16/92);

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10. Montgomery Hospital (Adm. 01/09/95);
11. Philadelphia Newspapers, Inc.;
12. Charter Fairmount Institute;
13. Nazareth Hospital Radiology;
14. Allegheny University Hospital - f/k/a Medical College of PA (O/P 01/07/86);
15. Allegheny University Hospital - f/k/a Medical College of PA (Adm. 01/08/86);
16. Montgomery Hospital Radiology - a/k/a Fornance Radiology Group;
17. Philadelphia School District of Records Management Div.;
18. Summerdale Pharmacy;
19. Charter Fairmount Institute (Adm. 01/17/86);
20. Wills Eye Hospital (ER 5/22/89);
21. Wells Fargo Guard Services;
22. Northeast Imaging;
23. Allied Security, Inc.;
24. Allegheny N.E. Medical Ctr. A/k/a N.E. Medical - Surgical Assocs.;
25. Video Deposition of Edward Slivak 6/18/97;
26. Soll Eye Associates;
27. Montgomery County Hospital 4/14/97 - 4/15/97; and
28. Dr. Marie Savard's report.

I have also reviewed documents concerning this litigation including reports of expert witnesses and deposition testimony. The history set forth in this report has been obtained from the records and deposition testimony.

I have reviewed the July 15, 1997 report of Dr. Savard concerning

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Mr. Edward Slivak in which she summarizes Mr. Slivak's medical history and I will not be repeating that medical history.

Mr. Slivak is a fifty-five year old married man who stated he was taking medication for Heart Disease, blood thinner and for his circulation at the time of my evaluation. He states those medications are currently prescribed to him by Doctors Moss and Cross. He is seen by them on a monthly basis.

The records identify that Mr. Slivak has smoked cigarettes for approximately forty years, beginning in his teenage years. He identified that he smokes between twelve cigarettes to a pack and a half daily. He has been advised to stop smoking by a number of physicians. He has used patches on two or three occasions, acupuncture and fake cigarettes. He says the longest period of time he has stopped smoking was for approximately ten days. He said he never went three weeks without cigarettes. The times he stopped smoking coincided with his medical problems.

Records identify that Mr. Slivak has been evaluated and treated for emotional and substance abuse problems. A diagnoses of an Adjustment Disorder with Depressed Mood and Alcohol Abuse was made. He said he got depressed while drinking and made suicide attempts. He had a history of losses, including his wife, mother, step-father, and his son was burned over fifty percent of his body.

In January 1986, he received in-patient psychiatric treatment at the Eastern Pennsylvania Psychiatric Institute (EPPI). A diagnosis of Adjustment Disorder with depression was made. He said his wife had died of breast cancer four years earlier. He was also having problems with his girlfriend and he had not received a promotion at work. He went into the Army at age eighteen and was also not promoted because of Article 15, for drinking.

After his discharge from EPPI, he was admitted to the Charter Fairmount Institute. He provided a history of using marijuana one to two times monthly and alcohol on a daily basis. He was treated for his alcoholism and depression. During my evaluation, he expressed his opinion that he had no problems with alcoholism. He states that he can't drink liquor which causes him to throw-up. However, he does drink two to three beers with out any problem. He did not think he had a problem with his alcohol consumption. Following his discharge from the Charter Fairmount Institute he did not receive any follow-up treatment. It is my opinion that Mr. Slivak continues to have problems with his alcohol consumption.

Mr. Slivak said that his understanding of addiction is that it is a necessity or an uncontrollable desire to have something. He

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states that a cigarette is like a drug and that it is like drug dependence. He states that there are forty-one or forty-two elements in cigarettes that have been placed there by the tobacco companies to make people become drug dependent. He said nicotine, tar and ammonium are some of the additives. He expressed his opinion that he could be addicted to other substances that are used day-to-day such as coffee, tea and soda. He expressed his opinion that in order to stop smoking, he would have to go into a rehabilitation program for fourteen to twenty-eight days. When questioned why he is unable to stop, he states he is used to smoking and it's tough to accept that he has no control and he is addicted. He states he has blamed others, but it is his fault. He states that it is something that has happened and he expressed his opinion that he needs something to stop smoking cigarettes.

He states that he has been "lazy" when dealing with his health issues. He says he has tried to go on a diet to lose weight and to eliminate the amount of red meat in his diet but has been unsuccessful. He is aware of other individuals who have stopped smoking including his supervisor and a sister. He does not know why he has not stopped smoking.

Mental status examination reveals Mr. Slivak to be a well groomed man who was five foot eight inches tall and weighed approximately 198 pounds and was right handed. He was cooperative throughout the course of the examination. His speech varied appropriately in its rate and volume. His facial expressions were appropriate during the interview. He maintained good eye contact. He demonstrated no psychomotor agitation or retardation. He was mildly anxious about being evaluated, otherwise his affect varied appropriately throughout the examination. He demonstrated a wide range of affect and had no evidence of any anxiety or depressive features. He could understand all of the questions that were asked of him and was able to respond with timely and relevant answers. His thinking was organized. There was no evidence of psychotic features such as delusions nor hallucinations. He was oriented to time, place and person.

In addition to my clinical psychiatric examination, psychological testing was administered utilizing the Minnesota Multiphasic Personality Inventory-2 (MMPI-2). A copy of the interpretive report of the psychological testing is enclosed. The testing reveals a valid profile. Symptomatic patterns identified that he felt nervous, tense , unhappy and worried, overly sensitive to criticism and blamed himself a great deal and feels that he has not been treated well. His depressed mood was accompanied by physical complaints and extreme fatigue. He relies upon denial and repression to deal with anxiety and conflict. He may seek medical

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attention for his "run-down" condition, but his physical problems were likely related to his depressed mood. He is passive-dependent in relationships, was nonassertive and easily hurt by others. Diagnostic considerations included a Dysthymic Disorder and the possibility of alcohol abuse were raised.

Based on the results of my clinical evaluation, the results of the psychological testing, my review of the records, depositions and reports which were previously listed, my training, education, and experience, it is my opinion, which I express with a reasonable degree of psychiatric certainty, that Mr. Edward Slivak has no evidence of a "dependance" or "addiction" to cigarettes. He has a history of treatment for emotional and alcohol problems. He has been advised by multiple physicians to stop smoking. He is also aware of the warnings concerning cigarette smoking. Mr. Slivak has not made a decision to stop smoking, nor has he implemented the necessary behavioral changes. He has had limited motivation to stop smoking.

Upon receipt and review of any additional reports or records, if indicated, I would be happy to provide an addendum to this report.

Sincerely yours,

Timothy J. Michals, M.D.

TJM/psd
Enclosure

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MMPI-2™

MINNESOTA MULTIPHASIC PERSONALITY INVENTORY-2™

By Starke R. Hathaway and J. Charnley McKinley

THE MINNESOTA REPORT™:
ADULT CLINICAL SYSTEM
INTERPRETIVE REPORT

By James N. Butcher

Client ID: 000002672
Report Date: 13-AUG-97
Age: 55
Sex: Male
Setting: General Medical
Education: 11
Marital Status: Married

ED SLIVAK

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MINNESOTA MULTIPHASIC PERSONALITY INVENTORY-2
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Printed in the United States of America.

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TM
MMPI-2 TM
THE MINNESOTA REPORT:
ADULT CLINICAL SYSTEM
INTERPRETIVE REPORT

ID: 000002672 REPORT DATE: 13-AUG-97

PROFILE VALIDITY

This client's approach to the MMPI-2 was open and cooperative. The resulting MMPI-2 profile is valid and probably a good indication of his present level of personality functioning. This may be viewed as a positive indication of his involvement with the evaluation.

SYMPTOMATIC PATTERNS

The client feels nervous, tense, and unhappy, and is quite worried at this time. He also appears to be quite indifferent to many of the things he once enjoyed and believes he is no longer able to function well in life. Overly sensitive to criticism, he tends to blame himself a great deal and feels that he has not been treated well. His depressed mood is accompanied by physical complaints and extreme fatigue.

He appears to be inhibited and overcontrolled, relying upon denial and repression to deal with anxiety and conflict. He may seek medical attention for his "run-down" condition, but his physical problems are likely to be related to his depressed mood.

In addition, the following description is suggested by the content of this client's responses. He views his physical health as failing and reports numerous somatic concerns. He feels that life is no longer worthwhile and that he is losing control of his thought processes. He asserts a high degree of social skill and tends to deny any problems interacting with other people. He complains about feeling quite uncomfortable and in poor health. The symptoms he reports reflect vague weakness, fatigue, and difficulties in concentration. In addition, he feels that others are unsympathetic toward his perceived health problems.

INTERPERSONAL RELATIONS

He is passive-dependent in relationships and is easily hurt by others. He is nonassertive and keeps anger bottled up, avoiding confrontation for fear of being rejected or hurt. He appears to be somewhat immature and may depend considerably upon his wife to take care of him. Many married persons with this profile have difficulties with their marriage. They typically show a diminished interest in sex and have little energy to expend making their marital partner happy. Moreover, his moodiness and whining are likely to place additional strains on the marriage.

BEHAVIORAL STABILITY

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INTERPRETIVE REPORT

ID: 000002672 REPORT DATE: 13-AUG-97

This profile pattern suggests persistent personality problems in his clinical picture.

The relative scale elevation of his highest clinical scale scores suggests clear profile definition. His most elevated clinical scales are likely to be present in his profile pattern if he is retested at a later date. His interpersonal style is not likely to change significantly if he is retested at a later date.

DIAGNOSTIC CONSIDERATIONS

Many individuals with this profile will present with psychophysiologic symptoms. Possible organic factors should be evaluated since some individuals with this profile pattern eventually develop psychophysiological disorders. The most frequent diagnosis for individuals with this profile type is Dysthymic Disorder. Physically disabling conditions related to psychological stress, such as ulcers or hypertension, may be part of the clinical pattern.

There is some possibility that he is having difficulties of an addictive nature. He may be abusing or over-using addicting substances. Further evaluation of alcohol or drug usage is recommended.

TREATMENT CONSIDERATIONS

He is rather uninsightful and may view his problems as largely physical. Many individuals with this pattern present with psychophysiologic disorders and should be carefully evaluated by a physician for possible medical problems.

Individuals with this MMPI-2 profile tend to feel quite tense and depressed and may need relief for their psychological symptoms. Perhaps the most frequent form of treatment given to individuals with this pattern is antidepressant medication. Many patients with this profile require a great deal of reassurance. They tend to lack insight into their behavior and will tolerate a great deal of tension before they will seek to improve themselves. Some individuals with this profile respond to a directive, action-oriented treatment approach and possibly to assertiveness training.

NOTE: This MMPI-2 interpretation can serve as a useful source of hypotheses about clients. This report is based on objectively derived scale indexes and scale interpretations that have been developed in diverse groups of patients. The personality descriptions, inferences and recommendations contained herein need to be verified by other sources of clinical information since individual clients may not fully match the prototype. The information in this report should most appropriately be used by a trained, qualified test interpreter. The information contained in this report should

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ID: 000002672 REPORT DATE: 13-AUG-97

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September 3, 1997

Howard M. Klein, Esquire
Conrad, O'Brien, Gellman & Rohn, P.C.
1515 Market Street, 16th Floor
Philadelphia, PA 19102-1916

RE: Ciaran McNally
Barnes et al v. The American Tobacco Company et al

Dear Mr. Klein:

At your request and pursuant to the court order, I have conducted a psychiatric evaluation of Ms. Ciaran McNally concerning this litigation. I conducted a clinical evaluation of Ms. McNally in my office on August 19, 1997. Prior to my examination, I informed her that I was a psychiatrist and had been asked by your office to evaluate her concerning this litigation, that I would not be treating her and that what we discussed was not confidential since I would be sending a report of my evaluation to your office and could be called to testify in this litigation. She understood the purpose of the examination and gave her consent to be examined. My examination has consisted of a clinical evaluation conducted on August 19, 1997, psychological testing utilizing the Minnesota Multiphasic Personality Inventory-2 (MMPI-2), and my review of the following records and reports:

1. Holy Cross School;
2. Bishop McDevitt High School;
3. Community college of Philadelphia;
4. Blue Shield of Pennsylvania;
5. Chestnut Hill Hospital/Pathology;
6. Chestnut Hill Hospital/Radiology;
7. Chestnut Hill Hospital/Business Office;
8. Chestnut Hill Pediatric Group;

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9. Independence Blue Cross a/k/a Blue Cross of Greater Philadelphia;
10. CVS Pharmacy #196 Store;
11. Harry A. Frankel, M.D.;
12. Richard L. Montozzi, M.D.;
13. Andrew K. Pollack, M.D. & Assoc.;
14. Greenhouse Internists, P.C.;
15. Hahnemann Orthopedic Assoc, P.C.;
16. Northwest Surgical Assoc., P.C.
17. Springmont OB-GYN;
18. Philadelphia Newspapers, Inc.;
19. Richard Gabriel Associates;
20. SmithKline Beecham Clinical Labs;
21. United Artist Theatre Circuit, Inc.;
22. Claims Pro;
23. Richard K. Krauss, M.D.;
24. Cytodiagnostics, Inc.;
25. Video Tape Deposition of Ciaran McNally 7/7/97;
26. Dr. Marie Savard's report;
27. Chestnut Hill College/ Chestnut Health Services; and
28. Chestnut Hill College.

I have also reviewed documents concerning this litigation including reports of expert witnesses and deposition testimony. The history set forth in this report has been obtained from the records and deposition testimony.

I have reviewed the July 15, 1997 report of Dr. Savard concerning her evaluation of Ms. Ciaran McNally in which she summarizes Ms.

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Stanford https://www.industrydocuments.ucsf.edu/docs/zkxl0001

McNally's medical history. I will not be repeating that medical history.

Ms. McNally is a twenty-six year old divorced female who is taking oral contraceptives at the time of my examination. She is followed medically by Dr. Day in Mount Airy and is not receiving any active medical treatment.

Ms. McNally started smoking at age eleven in 1981, at that time she smoked one cigarette. At the age of fourteen she smoked ten to fifteen cigarettes daily and has since that time. She said that she attempted to stop smoking on three or four occasions. She first tried to stop smoking when she was in college and stopped for approximately four days. She went to a Smoke Enders Program in 1995 and started smoking immediately after leaving the session. She has not attempted to utilize any methods to stop smoking such as patches, gum or hypnosis. She states that she has no idea how she would be able to stop smoking. She understands addiction to be something that the mind and body cannot do without, without experiencing painful physical symptoms. She stated that she was light-headed and dizzy when she stopped smoking for a week. She states that she now knows why she smokes and it is that she is addicted to cigarettes. Her parents and a sister have stopped smoking. She states that she does not know why she cannot stop smoking while other members of her family have.

She denies a history of ever using any drugs nor does she provide a history of having any problems related to her alcohol consumption.

Mental status examination reveals Ms. McNally to be a casually groomed woman who was cooperative throughout the course of the examination. Her speech varied appropriately in its rate and volume. Her facial expression was appropriate during the interview. She maintained good eye contact. She sat in a rigid position with her arms across the body throughout the evaluation. She was able to concentrate and respond to my questions with timely and relevant answers. She was able to provide an organized history, and her memory for recent and past events was intact. Her affect varied appropriately with what she was discussing and she demonstrated a full range of affect. She exhibited no anxiety of depressive features. There was no evidence of psychotic features such as delusions nor hallucinations.

In addition to my clinical psychiatric examination, psychological testing was administered utilizing the Minnesota Multiphasic Personality Inventory-2 (MMPI-2). A copy of the interpretive report of the psychological testing is enclosed. The testing

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reveals that Ms. McNally tends to place herself in an overly positive light by minimizing faults and denying psychological problems. The defensive stance is characteristic of individuals who are trying to maintain the appearance of adequacy and self-control. Ms. McNally tends to deny problems and is not very introspective or insightful about her behavior. The profile was within normal limits.

Based on the results of my clinical evaluation, the results of the psychological testing, the review of the records, depositions and reports previously listed, my training, education, and experience, it is, my opinion, which I express with a reasonable degree of psychiatric certainty, that Ms. McNally has no evidence of a "dependence" or "addiction" to cigarettes. Ms. McNally has made no significant efforts to stop cigarette smoking. In fact, she lit up a cigarette after leaving a Smoke Enders Program. She has known since she has been a teenager that cigarettes could cause health problems. She has used oral contraceptives and is aware of potential health problems associated with cigarette smoking and has chosen not to stop smoking. It is my opinion that Ms. McNally has not made the decision to commit herself to stop smoking, nor is she sufficiently motivated to stop smoking. She is aware of family members who have stopped smoking as well as warnings concerning health risks related to cigarette smoking. However, she has not made a significant commitment to change her behavior related to stopping her cigarette smoking.

I will be happy to provide any additional information you may require.

Sincerely yours,

Timothy J. Michals, M.D.

TJM/pad
Enclosure

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MINNESOTA MULTIPHASIC PERSONALITY INVENTORY-2™

By Starke R. Hathaway and J. Charnley McKinley

THE MINNESOTA REPORT™:
ADULT CLINICAL SYSTEM
INTERPRETIVE REPORT

By James N. Butcher

Client ID:	000002684
Report Date:	19-AUG-97
Age:	26
Sex:	Female
Setting:	General Medical
Education:	16
Marital Status:	Divorced

Ciara McNally

52601 1292

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THE MINNESOTA REPORT:
ADULT CLINICAL SYSTEM
INTERPRETIVE REPORT

ID: 000002684 REPORT DATE: 19-AUG-97

PROFILE VALIDITY

This profile has marginal validity since the client attempted to place herself in an overly positive light by minimizing faults and denying psychological problems. This defensive stance is characteristic of individuals who are trying to maintain the appearance of adequacy and self-control. This client tends to deny problems and is not very introspective or insightful about her own behavior.

The clinical profile is likely to be an underestimate of the individual's psychological problems. The individual is likely to have little awareness of her difficulties. The client is likely to be rigid and inflexible in her approach to problems and may not be open to psychological self-evaluation. She is likely to project an excessively positive self-image and to be somewhat arrogant and intolerant of others' failings. She is unlikely to seek psychological treatment or to cooperate fully with treatment if it is imposed on her.

Individuals with this level of defensiveness, as reflected in her high K score, tend to admit few MMPI-2 content themes. Thus, her content scale scores are likely to be under representative of her actual problems.

SYMPTOMATIC PATTERNS

Individuals with this MMPI-2 profile are not admitting to many psychological symptoms or problems. Her profile is within the normal range, suggesting that she views her present adjustment as adequate.

She appears to have no sex-role conflicts. Her range of interests includes, but is not limited to, homemaking and cultural activities.

In addition, the following description is suggested by the content of this client's responses. The client does not appear to be an overly anxious person prone to developing unrealistic fears. Any fears she reports are more likely to be viewed by her as reality-based rather than internally generated.

INTERPERSONAL RELATIONS

Quite outgoing and sociable, she has a strong need to be around others. She is gregarious and enjoys interpersonal attention.

BEHAVIORAL STABILITY

Confidential

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The relative scale elevation of her highest clinical scale scores suggests clear profile definition. Her most elevated clinical scales are likely to be present in her profile pattern if she is retested at a later date. Social introversion-extraversion tends to be a very stable personality characteristic over time. The client's typically outgoing and sociable behavior is likely to remain similar if she is retested at a later time.

DIAGNOSTIC CONSIDERATIONS

Her MMPI-2 profile is within normal limits. No clinical diagnosis is provided for individuals in this elevation range.

TREATMENT CONSIDERATIONS

Individuals with MMPI-2 profiles similar to this pattern are admitting few psychological problems. She views her adjustment as adequate and probably does not feel the need for mental health treatment at this time.

NOTE: This MMPI-2 interpretation can serve as a useful source of hypotheses about clients. This report is based on objectively derived scale indexes and scale interpretations that have been developed in diverse groups of patients. The personality descriptions, inferences and recommendations contained herein need to be verified by other sources of clinical information since individual clients may not fully match the prototype. The information in this report should most appropriately be used by a trained, qualified test interpreter. The information contained in this report should be considered confidential.

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125 South 9th Street
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Produced by R.J. Reynolds

September 3, 1997

Howard M. Klein, Esquire
Conrad, O'Brien, Gellman & Rohn, P.C.
1515 Market Street, 16th Floor
Philadelphia, PA 19102-1916

RE: **Norma Rodweller**
Barnes et al v. The American Tobacco Company et al

Dear Mr. Klein:

At your request and pursuant to the court order, I have conducted a psychiatric evaluation of Ms. Norma Rodweller concerning this litigation. I conducted a clinical evaluation of Ms. Rodweller in my office on August 13, 1997. Prior to my examination, I informed her that I was a psychiatrist and had been asked by your office to evaluate her concerning this litigation, that I would not be treating her and that what we discussed was not confidential since I would be sending a report of my evaluation to your office and could be called to testify in this litigation. She understood the purpose of the examination and gave her consent to be examined. My examination has consisted of a clinical evaluation conducted on August 13, 1997, psychological testing utilizing the Minnesota Multiphasic Personality Inventory-2 (MMPI-2), and my review of the following records and reports:

1. TJUH - Rheumatology Records;
2. Graduate Hospital Pathology;
3. TJUH Business Office;
4. Frankford Hospital - Frankford Campus (Adm. 04/27/94);
5. Frankford Hospital - Frankford Campus (ER Visit 11/11/95);
6. Franklin Mills Corp.;
7. Graduate Hospital (O/P Visit 10/07/93);
8. Graduate Hospital Gastroeterology;
9. Graduate Hospital - Pathology;

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10. Graduate Hospital Business Office;

11. Graduate Health Systems-Parkview Hospital;Business Office;

12. Graduate Health Systems-Parkview Hospital(f/k/a Metro. Hospital - Parkview;

13. Graduate Health Systems-Parkview Hospital(f/k/a Metro. Hospital - Parkview adm. 6/22/90;

14. Graduate Health Systems-Parkview Hospital(f/k/a Metro. Hosp. - Parkview O/P & ER visits, 12/17/90, 08/23/93, 09/12/93);

15. Graduate Health System - Parkview Hospital (f/k/a Metro. Hosp. - Parkview Business office;

16. Phar-Mor Pharmacy;

17. TJUH Cytology;

18. Allegheny N. E. Medical Practice;

19. Ear, Nose & Throat Consultants, Inc;

20. Frankford Hospital - Frankford Campus Business Office;

21. Naidoff Eye Health Associates;

22. Gastroenterology, Ltd.;

23. Allan Koff, D.O.;

24. Delaware Valley Cardiology Group, Inc.;

25. Burton Zweiman, M.D.;

26. Frank Guinn, D.O.;

27. Jeffrey Melin, M.D.;

28. Nazareth Hospital Radiology;

29. Nazareth Hospital (ER 03/05/90, 06/10/90, 06/15/90, 06/21/90);

30. Harris Ross, D.O.;

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31. Joel Shockman, M.D.;
32. Unicare Life & Health Insurance Co.;
33. Albert Sarkessian, D.O.;
34. Frankford Hospital - WorkHealth, Inc.;
35. SmithKline Beecham Clinical Labs;
36. PM & R Associates, LTD;
37. Physician Medical Billing;
38. Lincoln National Life Insurance Co.;
39. State Workman's Insurance Fund;
40. TJUH, Jefferson Obstetrics & GYN Associates;
41. Kemper Insurance Group;
42. Unicare Life & Health Insurance co;
43. Diagnostic Imaging, Inc.;
44. Mills Corp. f/k/a Western Development Corp.;
45. ITT Hartford Insurance Group - King of Prussia;
46. Copy of video deposition of Norma Rodweller 06/17/97;
47. Copy of Dr. Marie Savard's report; and
48. Benjamin S. Chack, D.O.

I have also reviewed documents concerning this litigation including reports of expert witnesses and deposition testimony. The history set forth in this report has been obtained from the records and deposition testimony.

I have reviewed the report of Dr. Savard concerning her evaluation of Ms. Rodweller in which she summarizes Ms. Rodweller's medical history. Dr. Savard identifies that Ms. Rodweller has not been compliant with medical recommendations concerning her health issues.

Ms. Rodweller is a fifty-seven year old widowed female who is

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taking Elavil 50 mg at bedtime, Pepcid, arthritis and sinus medicine. She states the Elavil was prescribed to her by Dr. Chack for three years for Fibromyalgia. Pepcid was for abdominal pains and the sinus medication was for allergy.

Records identify that Ms. Rodweller has smoked since she was ten years of age. She has smoked a pack of cigarettes daily since the age of fourteen. She has attempted to stop smoking cigarettes by cutting down the number of cigarettes she smokes and by switching to brands with lower nicotine. She utilized acupuncture on one occasion in the late 1970's. However, she smoked on the way home from that treatment. Her doctor gave her a patch to use in 1990 and she continued smoking on the patch. She denied any other treatment approaches to stop smoking. She now smokes between one and one and a half packs of cigarettes daily.

She states that she is unable to stop smoking and that she could never stop smoking. She says that she initially thought that she was weak, but now she is addicted and she can not stop. She states she understands that addiction is when she is controlled by the tobacco. She states that she has no trouble stopping anything else in her life. She states that her life evolves around cigarette smoking. She describes herself as getting hyper and agitated if she does not smoke every hour. She states the cigarettes calm down her agitation and her nerves. She states that if she has a headache and she doesn't smoke, the headache increases in intensity and she feels lousy. She has been informed by doctors to stop smoking and is aware of warnings concerning cigarette smoking. She said that she would have to be placed on a nerve pill that would give the feeling that she was inhaling a cigarette. She said she is aware of people who have stopped smoking, including her late husband. She has four children that smoke and four that don't. She drinks up to four cups of tea daily but does not think that she is addicted to caffeine because she has no craving for tea.

Mental status examination reveals Ms. Rodweller to be a casually groomed woman who was cooperative throughout the course of the examination. She was somewhat agitated when providing her history. She identified that she was angry concerning this lawsuit. However, her affect was not fixed and varied appropriately throughout the examination. She demonstrated a wide range of affect including smiling and laughing. She was oriented to time place and person. She was able to provide an organized history, and her memory for recent and past events was intact. There was no evidence of psychotic features such as delusions nor hallucinations. Her thinking focused on her anger which she related to the cigarette companies and her belief that ammonium added to cigarettes caused ongoing physical problems.

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In addition to my clinical psychiatric examination, psychological testing was administered utilizing the Minnesota Multiphasic Personality Inventory-2 (MMPI-2). A copy of the interpretive report of the psychological testing is enclosed. The testing reveals a valid profile, but Ms. Rodweller may have attempted to present an unrealistically favorable picture of virtue and moral values. She presented a picture of multiple physical problems and a reduced level of psychological functioning. She may show La Belle Indifference concerning her physical complaints. She is described as somewhat passive-dependent and demanding in interpersonal relationships, and may attempt to control others by complaining about her physical symptoms. Personality patterns were long standing. Diagnostic considerations included Conversion Disorder or Somatization Disorder and a Dependent Personality Disorder. The testing recommended an evaluation of her alcohol and drug use.

Based on the results of my clinical evaluation, the results of the psychological testing, the review of the records and reports previously listed, my training, education, and experience, it is my opinion, which I express with a reasonable degree of psychiatric certainty that Ms. Rodweller has a long history of cigarette smoking and has made no significant attempts to stop smoking. She attributes her ongoing physical problems to cigarette smoking. She expresses the belief that ammonium has been added to the cigarettes and accounts for her ongoing physical complaints. She is angered and irritated concerning this belief. It is my opinion that Ms. Rodweller has not made the decision nor committed herself to stop smoking and she has no evidence of a "dependence" or "addiction" to cigarettes. It is my opinion that her belief concerning her physical complaints reflect the issue of secondary gain. Ms. Rodweller has not been sufficiently motivated to address and make the behavioral changes to stop smoking.

I will be happy to review any additional records and would forward a supplement if indicated.

Sincerely yours,

Timothy J. Michals, M.D.

TJM/psd
Enclosure

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MINNESOTA MULTIPHASIC PERSONALITY INVENTORY-2™

By Starke R. Hathaway and J. Charnley McKinley

THE MINNESOTA REPORT™:
ADULT CLINICAL SYSTEM
INTERPRETIVE REPORT

By James N. Butcher

Client ID:	000002676
Report Date:	13-AUG-97
Age:	57
Sex:	Female
Setting:	General Medical
Education:	08
Marital Status:	Widowed

Norma Rosnick

52601 1300

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THE MINNESOTA REPORT:
ADULT CLINICAL SYSTEM
INTERPRETIVE REPORT

ID: 000002676 REPORT DATE: 13-AUG-97

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PROFILE VALIDITY

This is a valid MMPI-2 profile, but the client may have attempted to present an unrealistically favorable picture of her personal virtue and moral values. She may feel the need to present an image of strong moral character or to deny human frailties. Her approach to the MMPI-2 items suggests a rather naive or unsophisticated self-view.

SYMPTOMATIC PATTERNS

The client presents a picture of multiple physical problems and a reduced level of psychological functioning. Her physical problems may be vague, may have appeared suddenly after a period of stress, and may not be traceable to actual organic changes. She may be manifesting fatigue, vague pain, weakness, or unexplained periods of dizziness.

She may view herself as highly virtuous and show a "Pollyannish" attitude toward life. She may not appear greatly anxious or depressed over her symptoms and may show "la belle indifference." Apparently sociable and rather exhibitionistic, she seems to manage conflict by excessive denial and repression. She reports no significant sex-role conflicts.

In addition, the following description is suggested by the content of this client's responses. She views her physical health as failing and reports numerous somatic concerns. She feels that life is no longer worthwhile and that she is losing control of her thought processes. The client's response content suggests that she feels intensely fearful about a large number of objects and activities. This hypersensitivity and fearfulness appear to be generalized at this point and are likely to be quite debilitating to her in social and work situations.

INTERPERSONAL RELATIONS

She tends to be somewhat passive-dependent and demanding in interpersonal relationships. She may attempt to control others by complaining about physical symptoms.

She has an average interest in being with others and is not socially isolated or withdrawn. She appears to meet and talk with other people with relative ease and is not overly anxious when in social gatherings.

The content of this client's MMPI-2 responses suggests the following additional information concerning her interpersonal relations. She tends to approach social relationships with some caution and skepticism.

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INTERPRETIVE REPORT

ID: 000002676 REPORT DATE: 13-AUG-97

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BEHAVIORAL STABILITY

The personality pattern characterized by this profile is long-standing. The client is likely to have a hysteroid adjustment to life but under stress might experience periods of exacerbated symptom development. Some individuals with this profile develop a lifestyle of "invalidism" in which they become incapacitated and dependent upon others.

The relative scale elevation of the highest scales in her clinical profile reflects high profile definition. If she is retested at a later date, the peak scores on this test are likely to retain their relative salience in her retest profile pattern. Her interpersonal style is not likely to change significantly if she is retested at a later date.

DIAGNOSTIC CONSIDERATIONS

Individuals with this profile typically show a neurotic pattern of adjustment and would probably receive a clinical diagnosis of Conversion Disorder or Somatization Disorder. They might also receive an Axis II diagnosis of Dependent Personality.

There is some possibility that she is having difficulties of an addictive nature. She may be abusing or over-using addicting substances. Further evaluation of alcohol or drug usage is recommended.

TREATMENT CONSIDERATIONS

There is apparently a strong psychological component to her symptom pattern which should be carefully evaluated before medical procedures are implemented. Individuals with this MMPI-2 profile tend to be defensive toward psychological interpretations of their physical symptoms. They show reluctance to engage in self-exploration and are generally not very open to the idea that their own thinking may be influencing their problems. She shows little anxiety about her symptoms and is unmotivated to improve her personal adjustment.

She appears to be difficult to approach with long-term treatment goals or insight-oriented approaches to psychotherapy. However, if she is to make significant, enduring gains in personality adjustment, a long-term treatment commitment may be called for. In the beginning of therapy, individuals with this profile type may be too defensive to engage in productive self-reflection. They tend to lose interest in psychological treatment or continue to fall back on somatic explanations for their problems, particularly if treatment sessions are aimed at exploring emotional content.

In many cases, the somatic symptoms reflected in this profile pattern are influenced or exacerbated by environmental stress. Her low level of

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INTERPRETIVE REPORT

ID: 000002676 REPORT DATE: 13-AUG-97

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psychological functioning may be improved by stress inoculation therapy aimed at reducing her situational stress and providing her with more adaptive approaches to living.

Many individuals with this profile type persist in pursuing medical treatments for problems that have no organic basis. Some individuals with this extreme profile have been shown to have a poor response to any type of treatment.

NOTE: This MMPI-2 interpretation can serve as a useful source of hypotheses about clients. This report is based on objectively derived scale indexes and scale interpretations that have been developed in diverse groups of patients. The personality descriptions, inferences and recommendations contained herein need to be verified by other sources of clinical information since individual clients may not fully match the prototype. The information in this report should most appropriately be used by a trained, qualified test interpreter. The information contained in this report should be considered confidential.

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PRODUCED IN R.J.R.

September 3, 1997

Howard M. Klein, Esquire
Conrad, O'Brien, Gellman & Rohn, P.C.
1515 Market Street, 16th Floor
Philadelphia, PA 19102-1916

RE: William Barnes
Barnes et al v. The American Tobacco Company et al

Dear Mr. Klein:

At your request and pursuant to the court order, I have conducted a psychiatric evaluation of Mr. William Barnes concerning this litigation. I conducted a clinical evaluation of Mr. Barnes in my office on August 17, 1997. Prior to my examination, I informed him that I was a psychiatrist and had been asked by your office to evaluate him concerning this litigation, that I would not be treating him and that what we discussed was not confidential since I would be sending a report of my evaluation to your office and could be called to testify in this litigation. He understood the purpose of the examination and gave his consent to be examined. My examination has consisted of a clinical evaluation conducted on August 17, 1997, psychological testing utilizing the Minnesota Multiphasic Personality Inventory-2 (MMPI-2), and my review of the following records and reports:

1. Founders East f/k/a Police/Fire Medical Assn.;
2. Allegheny University Hospital - Elkins Park (f/k/a Rolling Hills Hospital (O/P Visits);
3. Allegheny University Hospital - Elkins Park (f/k/a Rolling Hills Hospital (Adm. 04/12/95);
4. Allegheny University Hospital - Elkins Park (f/k/a Rolling Hills Hospital (Adm. 08/26/95, 11/5/96);
5. Germantown Professional Associates, Ltd.;
6. Pathmark Pharmacy;
7. QualMed Plans for Health of PA;
8. Philadelphia School District of Records Mgmt. Div.;

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9. City of Philadelphia Police Personnel Office;

10. SmithKline Beecham Clinical Labs.;

11. Allegheny University Hospital - Elkins Park (f/k/a Rolling Hills Hospital - Business Office;

12. Video Tape Deposition of William Barnes 6/17/97;

13. Allegheny University Hospital - Elkins Park billing records;

14. Veterans Affairs Regional Office Cent.; and

15. Dr. Maria Savard's report.

I have also reviewed documents concerning this litigation including reports of expert witnesses and deposition testimony. The history set forth in this report has been obtained from the records and deposition testimony.

I have reviewed the report of Dr. Savard concerning her evaluation of Mr. William Barnes in which she summarizes Mr. Barnes' medical history and I will not be repeating that medical history.

Mr Barnes is a fifty year old married male who is currently taking medication for hypertension. He states that Dr. Winokur has prescribed that medication for him. He has been treated for hypertension for a number of years. He is being followed by Dr. Winokur at the Police and Fireman's Clinic. Mr. Barnes recently has submitted his resignation from the Philadelphia Police Department. He is currently utilizing his accumulated leave time. He is currently employed as an Enforcement Officer by the Commonwealth of Pennsylvania Public Utility Commission and has worked in that position since July 15.

The records and reports identify that Mr. Barnes smoked one cigarette daily when he was ten years of age. He stated that he and three of his friends would smoke one cigarette on their way home from school. He did not smoke on a regular basis until he was in the Army. The medical records are inconsistent in the amount of cigarette smoking that Mr. Barnes has claimed. Records identify that he had smoked from three cigarettes daily to one pack per day.

While working as a police officer, he was in charge of enforcing the no smoking policy in the district headquarters. He is also not permitted to smoke in his current employment position. He states

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that he has attempted to stop smoking in the past by going "cold turkey." He said seven hours was the longest period of time that he refrained from smoking. He states that he has been able to stop other bad habits but he is unable to discontinue smoking on his own. It is his opinion that there are additives placed into cigarettes to make a person more addicted. He expressed his opinion that he is addicted to cigarette smoking. He defines addiction as wanting to smoke and to inhale some smoke into his lungs. He states that he likes how it feels when he smokes. He has been instructed by physicians to stop smoking.

He provides a history of drinking alcohol for a number of years. He said that he would go to local bars with other police officers after they had completed their shift. He decided to stop drinking on December 31, 1996. At that time, he stated that he was learning to play the saxophone and would miss notes. He said that his teacher questioned what was wrong. Mr. Barnes thought he was playing well. He said there is a difference in his ability to play since he stopped drinking alcohol. Additionally, he said that a "turnkey" at work developed a liver problem and died as a result of his alcohol consumption and Mr. Barnes did not want to end up like that.

Mr. Barnes was admitted to the Medical College Hospital, Elkins Park Campus in January of 1997, after experiencing a grand mal seizure. Records identify that the probable cause of the seizure was an alcohol withdrawal syndrome. Mr. Barnes expresses his opinion that he did not have any problems with his alcohol consumption, which is inconsistent with the findings in the medical records. He has not been involved in an alcohol treatment program since his discharge from the hospital. He states that he still goes to bars, but does not drink.

Mr. Barnes stated that his wife was a former smoker and stopped smoking on her own without any assistance. He stated that one night, she was looking for a cigarette and going through butts in an ashtray. He stated that she got disgusted with herself and stated that she was not going to smoke. She stopped smoking at that point. Additionally, he stated that his sisters have stopped smoking, and the other former police officers that he is currently working with have also stopped smoking. He says that none of these people who have stopped smoking have been in any treatment programs.

Mr. Barnes stated that he was going to stop smoking and was going to use the Nicoret Gum. He said that the gum was not covered under his health insurance plan and cost $62. He said he did not have the money to purchase the gum.

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Mental status examination reveals Mr. Barnes to be a casually groomed man who was six foot two inches tall and weighed approximately 214 pounds and was right handed. He was cooperative throughout the course of the examination. His speech varied appropriately in its rate and volume. His facial expression was appropriate during the interview. He maintained good eye contact. He demonstrated no psychomotor agitation or retardation. He demonstrated a wide range of affect that was appropriate to what he was discussing. He had no evidence of any anxiety or depressive features. He was able to respond to my questions with timely and relevant answers. His thinking was organized. He was able to provide an organized history and his memory for recent and past events was intact. There was no evidence of psychotic features such as delusions nor hallucinations. He was oriented to time, place and person. His thinking with regard to cigarette smoking focused on his idea that he was unable to stop smoking on his own and the reason he was unable to stop smoking was because of the additives placed in cigarettes by the tobacco companies.

In addition to my clinical psychiatric examination, psychological testing was administered utilizing the Minnesota Multiphasic Personality Inventory-2 (MMPI-2). A copy of the interpretive report of the psychological testing is enclosed. The clinical profile is within normal limits.

Based on the results of my clinical evaluation, the results of the psychological testing, the review of the records, depositions, and reports previously listed, my training, education, and experience, it is my opinion, which I express with a reasonable degree of psychiatric certainty, that Mr. William Barnes has no evidence of a "dependence" or "addiction" to cigarettes. It is my opinion that Mr. Barnes has not chosen nor made a decision to stop his cigarette smoking. He has not made the commitment to change his behavior with regard to his cigarette smoking. He is aware that cigarette smoking can be discontinued as evidenced by his wife, family members and co-workers cessation without any treatment programs. Mr. Barnes has been informed by his physicians of the risks of cigarette smoking and he is aware of the warning labels on cigarette packages and yet, he has not made the commitment to discontinue his cigarette smoking. My evaluation did not identify that Mr. Barnes has made a serious commitment to change his behavior with regard to his cigarette smoking.

Tobacco Litigation

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I will be happy to review any additional records and, if indicated would provide a supplemental report.

Sincerely yours,

Timothy J. Michals, M.D.

TJM/psd
Enclosure

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MMPI-2™

MINNESOTA MULTIPHASIC PERSONALITY INVENTORY-2™

By Starke R. Hathaway and J. Charnley McKinley

THE MINNESOTA REPORT:™
ADULT CLINICAL SYSTEM
INTERPRETIVE REPORT

By James N. Butcher

Client ID:	000002680
Report Date:	18-AUG-97
Age:	50
Sex:	Male
Setting:	General Medical
Education:	12
Marital Status:	Married

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THE MINNESOTA REPORT:™
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INTERPRETIVE REPORT

ID: 000002680 REPORT DATE: 18-AUG-97

PROFILE VALIDITY

He has endorsed a number of psychological symptoms in a generally frank and open manner. His profile is likely to be problem oriented rather than defensive. His clinical profile is likely to be a valid indication of his present personality functioning.

SYMPTOMATIC PATTERNS

The client's MMPI-2 clinical scales are within normal limits, however, he has endorsed some item content that may be important to consider in this evaluation.

He appears to be more interested in abstract matters than practical activities. He has a somewhat unconventional approach to life and may view problems in a creative and unusual way. He may appear dreamy and preoccupied and may show some dissatisfaction with life. He appears to have no sex-role conflicts.

INTERPERSONAL RELATIONS

He has an average interest in being with others and is not socially isolated or withdrawn. He appears to meet and talk with other people with relative ease and is not overly anxious when in social gatherings.

The content of this client's MMPI-2 responses suggests the following additional information concerning his interpersonal relations. He views his home life as pleasant and supportive at this time.

DIAGNOSTIC CONSIDERATIONS

This client's MMPI-2 clinical profile is within normal limits and no clinical diagnosis is provided.

NOTE: This MMPI-2 interpretation can serve as a useful source of hypotheses about clients. This report is based on objectively derived scale indexes and scale interpretations that have been developed in diverse groups of patients. The personality descriptions, inferences and recommendations contained herein need to be verified by other sources of clinical information since individual clients may not fully match the prototype. The information in this report should most appropriately be used by a trained, qualified test interpreter. The information contained in this report should

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ID: 000002680 REPORT DATE: 18-AUG-97

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PRODUCED PURSUANT TO P.R.J.C.

September 3, 1997

Howard M. Klein, Esquire
Conrad, O'Brien, Gellman & Rohn, P.C.
1515 Market Street, 16th Floor
Philadelphia, PA 19102-1916

RE: Catherine Potts
Barnes et al v. The American Tobacco Company et al

Dear Mr. Klein:

At your request and pursuant to the court order, I have conducted a psychiatric evaluation of Ms. Catherine Potts concerning this litigation. I conducted a clinical evaluation of Ms. Potts in her home in Fairless Hills on August 17, 1997. Prior to my examination, I informed her that I was a psychiatrist and had been asked by your office to evaluate her concerning this litigation, that I would not be treating her and that what we discussed was not confidential since I would be sending a report of my evaluation to your office and could be called to testify in this litigation. She understood the purpose of the examination and gave her consent to be examined. Mr. David Warren, an Investigator for attorneys representing Ms. Potts was present during the examination. However, he did not participate in the examination. My examination has consisted of a clinical evaluation conducted on August 17, 1997, psychological testing utilizing the Minnesota Multiphasic Personality Inventory-2 (MMPI-2), and my review of the following records and reports:

1. Morrisville Family Practice Records;
2. CVS Pharmacy #1207 Store Records;
3. St. Mary's Hospital Medical Records'
4. St. Mary's Hospital/Pathology;
5. St. Mary's Hospital/Radiology;
6. Gastroenterology Group;
7. Benjamin S. Chack, D.O.;
8. Bucks Radiation Oncology Association;

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9. Delaware Valley Medical Center (Adm. 11/02/88);
10. Delaware Valley Medical Center (O/P & ER Visits);
11. Delaware Valley Medical Center (Adm. 05/10/92);
12. Delaware Valley Medical Center (O/P & ER Visits);
13. Delaware Valley Medical Center (Adm. 04/11/94);
14. Delaware Valley Medical Center (O/P Visit 04/15/94);
15. Delaware Valley Medical Center (Adm. 04/16/94);
16. Delaware Valley Medical Center (O/P Visits, 09/29/94, 09/30/94, 10/03/94, 10/07/94);
17. Delaware Valley Medical Center (Adm. 04/18/95);
18. Delaware Valley Medical Center (O/P Visit 05/04/95 & 05/09/95);
19. Delaware Valley Medical Center (Adm. 05/15/95);
20. Delaware Valley Medical Center (O/P Visit 6/30/96);
21. Delaware Valley Medical Center (Adm. 03/21/96);
22. Delaware Valley Medical Center Business Office;
23. Allegheny University Regional Internal Medicine;
24. Bristol Township Public Schools;
25. St. Mary's Hospital Business Office;
26. U.S. Health Care;
27. Women's Specialists of Bucks County;
28. C.V. Surgical Associates, Inc.;
29. Twining Village;
30. Xact Medicare Services Medicare Part B;
31. Department of Public Welfare, Bureau of Financial Operations, TPL Sect;

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32. Lower Bucks Hospital Business Office;

33. Lower Bucks Hospital Radiology;

34. Radcliffe Family Practice, P.C.

35. Commonwealth of PA - Department of Public Welfare - Legal Counsel;

36. Fox Chase Cancer Center - American Oncologic Hospital;

37. Fox Chase Cancer Center - American Oncologic Hospital - Pathology;

38. Langhorne Drug Store;

39. Delaware Valley Medical Center - Radiology;

40. Bucks County Cardiology Association;

41. Parkway Clinical Labs;

42. Eastern State School & Hospital;

43. Segal Aaronson Pulmonary Associates;

44. Delaware Valley Medical Center - Pathology;

45. Delaware Valley Medical Center - Billing Records;

46. Delaware Valley Medical Center - Admissions (05/02/97 - 05/12/97 and 02/14/97 - 02/07/97);

47. Albert Einstein Medical Center - Northern Division Business Office;

48. Albert Einstein Medical Center - Northern Division Admission (01/25/89 - 01/27/89 and 02/05/89 - 02/08/89);

49. St Mary's Hospital;

50. Bucks County Gastroenterology Associates;

51. U.S. Health Care - Pages 00001-00076;

52. Lower Bucks Hospital - Outpatient Visits;

53. Delaware Valley Medical Center Page Nos. 00497A-K, 00139A, 00141A-L, 11468A, 00472A-B, 00497A-C;

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54. Delaware Valley Medical Center - Outpatient Visits; and

55. Copy of Dr. Marie Savard's report.

I have also reviewed documents concerning this litigation including reports of expert witnesses and deposition testimony. The history set forth in this report has been obtained from the records and deposition testimony.

I have reviewed the report of Dr. Savard concerning Ms. Potts in which she summarizes Ms. Potts' medical history. I will not be repeating that medical history.

Ms. Potts states that she was taking medication for her hypertension, heart disease and gastrointestinal complaints at the time of my evaluation. She states those medications have been prescribed to her by Dr. Pinciotti. She has been hospitalized on three occasions in 1997 for repair of a hernia. She was hospitalized at the Delaware Valley Medical Center and at the Hospital of the University of Pennsylvania. She stated that she required ventilation treatment during those hospitalizations. She did not smoke for approximately one month following her discharge from Delaware Valley Medical Center. In addition she did not smoke during her hospitalizations. She stated she was proud of herself that she did not smoke and did not believe that she was not smoking. She has no idea why she started smoking after that period of time.

The records identify that Ms. Potts started smoking at approximately fourteen years of age and has continued smoking since then. She stated that she started smoking because everyone else did. She states that she has been instructed by doctors to stop smoking for health reasons. She identifies that Dr. Chack, an Ear Nose and Throat physician, has warned her to stop smoking because of problems with her vocal cords and that her cancer could come back if she doesn't stop smoking. She stated that she should be scared enough to stop, but she has not. She states that people have told her that, "smoking is killing her," and that she knows it in her own head. She now expresses her opinion that she is addicted to cigarette smoking, but she never had that thought until this litigation. She equates her addiction as being addicted to such hard drugs as heroin or cocaine. She expresses the thought that there are four hundred substances in the cigarettes and is not sure what in the cigarettes is addicting. She quotes, "I guess that anything could be addicting." However she says, "I can take or leave other things, but not cigarettes." She identifies drugs, alcohol, sex and money as other potentially addicting substances. She does not think that caffeine is addicting.

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Mental status examination reveals Ms. Potts to be a casually groomed woman who was cooperative throughout the course of the examination. She stated she is five foot seven inches tall and weighed about 175 pounds and was right handed. She states that she has lost approximately fourteen pounds and relates that to her recent illnesses and hospitalizations. Her speech varied appropriately in its rate and volume. There is no evidence of any psychomotor agitation or retardation. Her facial expression was appropriate during the interview. She maintained good eye contact. She was able to concentrate and respond to my questions with timely and relevant answers. Her affect varied appropriately with what she was discussing and she demonstrated a full range of affect. She exhibited no anxiety or depressive features. There was no evidence of psychotic features such as delusions nor hallucinations. She is oriented to time, place and person. She relates her problems to smoking and the cigarette companies and expresses the opinion that she is unable to stop smoking.

Ms. Potts states that she has attempted to stop smoking on her own in the past. Except for her present illness, the most she has stopped smoking has been for a few days. She said that she tried hypnosis and stopped smoking for one week. She said doctors have told her not to use patches. She is aware of no methods that are currently available to help her stop smoking. She states a pill would have to be developed to enable her to stop smoking.

Records identify that Ms. Potts has a history of consuming beer for twenty years. A radiology report in April of 1995 identified a fatty and enlarged liver. In October of 1995, Ms. Potts was evaluated at the Behavioral Health Care at the Delaware Valley Medical Center. She was described as feeling depressed and had experienced significant losses including health, selling her home and financial concerns. She was diagnosed as having a Major Depressive Disorder. She had been prescribed Xanax and Prozac in November of 1995. In 1996, she was described as being anxious and depressed.

She has been treated for Carcinoma of the left vocal cord. She has been evaluated for Coronary Artery Disease, Chronic Obstructive Pulmonary Disease, hypertension and gastrointestinal bleeding, a breast mass, Osteoarthritis and hyperlipidemia. She has been advised to stop smoking and to cut down her alcohol consumption by a number of doctors. She has not been compliant with follow-up on medical evaluations and treatments that have been recommended.

In addition to my clinical psychiatric examination, psychological testing was administered utilizing the Minnesota Multiphasic Personality Inventory-2 (MMPI-2). A copy of the interpretive report of the psychological testing is enclosed. The testing

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reveals a valid profile. She may be evasive and unwilling to admit to many personal faults. She has a tendency to develop physical problems in stress situations. She relied on defenses of denial and repression in the face of conflicts. She is passive-dependent and demanding in interpersonal relationships. The profile suggested she uses physical complaints to influence and manipulate other people. Her behavioral pattern is thought to be stable over time, exacerbated with physical problems. Although she reported a number of specific physical and psychological symptoms, the pattern of complaints and her low level of distress did not allow for a clear diagnostic statement. The report viewed her problems as being physical in nature and was not thought to be very amenable to psychological treatment approaches. It was thought that she may be receiving secondary gain from her symptoms that helps to maintain those symptoms.

Based on the results of my clinical evaluation, the results of the psychological testing, the review of the records, depositions and reports previously listed, my training, education, and experience, it is my opinion, which I express with a reasonable degree of psychiatric certainty, that Ms. Potts has a long standing history of cigarette smoking and had been advised to stop smoking by doctors and has made no serious attempts to stop her cigarette smoking. She has been non-compliant with medical recommendations concerning smoking and other health issues. She has been diagnosed as having a Major Depressive Disorder and has been treated for that condition with anti-anxiety and anti-depressive medications. Ms. Potts has not made a committed decision to stop cigarette smoking despite being advised by numerous doctors. She expresses the thought that she is unable to stop smoking. It is my opinion that she has not demonstrated sufficient motivation nor has she made a commitment to discontinue her cigarette smoking. It is my opinion that Ms. Potts is neither "addicted" to nor "dependent" on cigarettes.

I will be happy to review any additional documents that you may forward. If indicated, following that review, I will provide an addendum for this report.

Sincerely yours,

Timothy J. Michals, M.D.

TJM/psd
Enclosure

PLAINTIFF'S EXHIBIT

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MINNESOTA MULTIPHASIC PERSONALITY INVENTORY-2™

By Starke R. Hathaway and J. Charnley McKinley

THE MINNESOTA REPORT:™ ADULT CLINICAL SYSTEM INTERPRETIVE REPORT

By James N. Butcher

Client ID:	000002683
Report Date:	19-AUG-97
Age:	59
Sex:	Female
Setting:	General Medical
Education:	10
Marital Status:	Divorced

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THE MINNESOTA REPORT:
ADULT CLINICAL SYSTEM
INTERPRETIVE REPORT

ID: 000002683 REPORT DATE: 19-AUG-97

PROFILE VALIDITY

This is a valid MMPI-2 profile. However, the client approached the items in a defensive and overly cautious manner. She may be evasive and unwilling to admit to many personal faults. Individuals with similar profiles are often uninterested in and unwilling to enter into discussion of their problems.

SYMPTOMATIC PATTERNS

The client's MMPI-2 profile suggests that the problems she is reporting are not as extreme as those of many psychiatric patients. However, she has a tendency to develop physical problems in stress situations. Her medical history is likely to be characterized by excessive and vague physical complaints, weakness, and pain.

Although she may not now be greatly incapacitated by her physical symptoms, she tends to rely on hysterical defenses of denial and repression in the face of conflict. She may show a "Pollyannish" attitude, even though she may express physical complaints that, if genuine, would trouble most other people. She reports no significant sex-role conflicts.

INTERPERSONAL RELATIONS

She is somewhat passive-dependent and demanding in relationships. Although she may at first appear skillful in handling social relationships, she tends to be rather immature, superficial, and unskilled with the opposite sex. Individuals with this profile tend to use physical complaints to influence or manipulate other people.

She has an average interest in being with others and is not socially isolated or withdrawn. She appears to meet and talk with other people with relative ease and is not overly anxious when in social gatherings.

BEHAVIORAL STABILITY

This pattern of behavior tends to be stable over time, with periods of exacerbated physical problems. High stress increases the likelihood that she will experience psychologically based physical symptoms. Individuals with this profile may, over time, show a pattern of somatic distress.

The relative scale elevation of her highest clinical scale scores suggests clear profile definition. Her most elevated clinical scales are likely to be present in her profile pattern if she is retested at a later date. Her interpersonal style is not likely to change significantly if she is retested at a later date.

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ADULT CLINICAL SYSTEM
INTERPRETIVE REPORT

ID: 000002683 REPORT DATE: 19-AUG-97

DIAGNOSTIC CONSIDERATIONS

Although she has reported a number of specific physical and psychological symptoms, the pattern of complaints and her relatively low level of distress as compared with other clients do not allow for a clear diagnostic statement.

TREATMENT CONSIDERATIONS

Since her presenting problem is likely to be somatic in nature, she may not be very amenable to psychological treatment approaches. Her tendency to repress or deny problems makes her particularly resistant to the idea that psychological factors can influence her symptoms. She does not appear to be very motivated for psychological change at this time. She may be receiving secondary gain from her symptoms that helps to maintain them.

Some individuals with this profile experience intractable pain in the absence of actual organic problems. Symptomatic treatment might include behavioral management of her symptoms in order to reduce the amount of learned pain behavior. Individuals with this profile type may experience an exacerbation of symptoms under stressful conditions. It may be possible to implement a stress inoculation program to assist her in reducing stress.

NOTE: This MMPI-2 interpretation can serve as a useful source of hypotheses about clients. This report is based on objectively derived scale indexes and scale interpretations that have been developed in diverse groups of patients. The personality descriptions, inferences and recommendations contained herein need to be verified by other sources of clinical information since individual clients may not fully match the prototype. The information in this report should most appropriately be used by a trained, qualified test interpreter. The information contained in this report should be considered confidential.

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produced in R.J. Reynolds Litigation

September 3, 1997

Howard M. Klein, Esquire
Conrad, O'Brien, Gellman & Rohn, P.C.
1515 Market Street, 16th Floor
Philadelphia, PA 19102-1916

RE: **Barbara Salzman**
Barnes et al v. The American Tobacco Company et al

Dear Mr. Klein:

At your request and pursuant to the court order, I have conducted a psychiatric evaluation of Ms. Barbara Salzman concerning this litigation. I conducted a clinical evaluation of Ms. Salzman in my office on August 13, 1997. Prior to my examination, I informed her that I was a psychiatrist and had been asked by your office to evaluate her concerning this litigation, that I would not be treating her and that what we discussed was not confidential since I would be sending a report of my evaluation to your office and could be called to testify in this matter in court. She understood the purpose of the examination and gave her consent to be examined. My examination has consisted of a clinical evaluation, psychological testing utilizing the Minnesota Multiphasic Personality Inventory-2 (MMPI-2), and my review of the following records and reports:

1. Obstetrics & GYN Assn. Records;
2. Jeanes Hospital Radiology;
3. Jeanes Hospital Business Office;
4. Jeanes Hospital Pathology;
5. Jeanes Hospital (O/P Visits, 6/4/91, 6/13/91, 6/24/91, 6/25/91, 6/27/91, 3/5/92, 3/19/92, 3/20/92, 3/23/92, 3/25/92, 10/19/92, 6/29/93, 12/22/94, 6/1/95, 6/1/96);
6. Philadelphia School District of Records Management Division;
7. U.S. Health Care;

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Substantial portions of www.industrydocuments.ucsf.edu/docs/zkxl0001

8. Bustleton Radiology Associates;
9. Bustleton Medical Center;
10. Manuel Rosenberg, M.D.;
11. Barry Abraham, M.D.;
12. Aramark Corp.;
13. Magdalene Ho, M.D.;
14. Orthopedic Surgical Associates, Ltd.;
15. Brent Weinerman, D.O.;
16. Albert Einstein Med. Ctr. (O/P 10/25/73;
17. Albert Einstein Med. Ctr. (Adm. 11/04/73);
18. Video Tape Deposition of Barbara Salzman 6/18/97;
19. Guardian Group Inc.;
20. Dr. Maria Savard's report; and
21. John Duffy, O.D.

I have also revfewed documents concerning this litigation including reports of expert witnesses and deposition testimony. The history set forth in this report has been obtained from the records and deposition testimony.

Ms. Barbara Salzman is a fifty-nine year old married female who is taking medication for treatment of hypertension. She states she is also being treated for arthritis which involves most of her body. Dr. Rosenberg is her treating physician.

I have reviewed the July 15, 1997 report of Dr. Savard concerning her evaluation of Ms. Barbara Salzman in which she summarizes Ms. Salzman's medical history and I will not be repeating that medical history.

The records identify that Ms. Salzman began smoking at the age of fourteen. She said her sisters smoked and that smoking made her feel like a big-shot and that it made her look pretty. She stated there was peer pressure. She says that she has attempted to quit

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smoking on several occasions. She used hypnosis, nicotine gum, patches, and a quit smoking program. She was able to stop smoking for three and a half years following her completion of the Smoke Enders Program. She expressed her opinion that she continued to be addicted during that three and a half year time. She stated that her body still craved cigarettes and she felt that she wanted a cigarette. She also stated that she was irritable and screamed at her children. She said she gained sixty-eight pounds when she stopped smoking. She said that she did not feel good and claimed that she had shakes everyday. She does not know why she started to smoke again.

She is aware of people who have discontinued smoking, including her husband. She said that her husband did not smoke as much as she did, smoking approximately one pack a week. He stopped smoking in March of 1997 after smoking for twenty years. He had a heart problem and stopped smoking in the hospital. She stated that he was not addicted, "not as much as she was." She stated that when he had his surgery, his lungs were perfectly clean and had no adverse effects from smoking. She stated that it must be in his genes.

She stated that when she started smoking, cigarettes were all tobacco. She states the tobacco is now mixed with a lot of chemicals. She states that she is aware that there is ammonium and vinegar in cigarettes and that the ammonium has to harm the body.

She told me at the time of her evaluation that in order for her to stop smoking, she would have to be involved in a program such as Alcoholics Anonymous and continue in a program such as Smoke Enders and maintain her involvement in that program. She said a program such as Alcoholic Anonymous should be ongoing and not time limited.

Ms. Salzman has been informed by doctors that she should stop smoking. She has told family members that she does not want to quit smoking. She does not think she has any problems related to smoking, including pulmonary problems.

Mental status examination reveals Ms. Salzman to be a casually groomed woman who was cooperative throughout the course of the examination. She manifested no psychomotor agitation or retardation. Her speech varied in its rate and volume. She was able to concentrate and respond to my questions with timely and relevant answers. She was able to provide an organized history, and her memory for recent and past events was intact. She maintained good eye contact throughout the examination. Her facial expressions varied appropriately during the examination. She

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demonstrated no anxiety or depressive features. She demonstrated no evidence of psychotic features such as delusions nor hallucinations.

In addition to my clinical psychiatric examination, psychological testing was administered utilizing the Minnesota Multiphasic Personality Inventory-2 (MMPI-2). A copy of the interpretive report of the psychological testing is enclosed. The testing reveals a valid profile and is within normal limits without any clinical diagnosis.

Based on the results of my clinical evaluation, the results of the psychological testing, the review of the records, depositions and reports previously listed, my training, education, and experience, it is my opinion, which I express with a reasonable degree of psychiatric certainty, that Ms. Salzman has no evidence of a "dependence" or "addiction" to cigarettes. Ms. Salzman has a long history of cigarette smoking and had been able to stop smoking for three and a half years. It is my opinion that her decision to re-start smoking was her voluntary choice and was not a result of "addiction" nor "dependence" to cigarettes. Ms. Salzman has known other people who have stopped smoking, including her husband. She has been advised by physicians and is aware of information concerning health risks related to cigarette smoking, but has not followed advice or warnings. Ms. Salzman's history that she has been able to stop smoking for three and a half years, is indicative that she has the capacity to stop smoking. Presently, she has not decided to again stop smoking and lacks the sufficient motivation to change her behavior to stop smoking. She has told her family that she does not want to quit smoking.

Upon receipt and review of any additional records, if indicated, I will be happy to forward an addendum to this report.

Sincerely yours,

Timothy J. Michals, M.D.

TJM/psd
Enclosure

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MINNESOTA MULTIPHASIC PERSONALITY INVENTORY-2™

By Starke R. Hathaway and J. Charnley McKinley

THE MINNESOTA REPORT™:
ADULT CLINICAL SYSTEM
INTERPRETIVE REPORT

By James N. Butcher

Client ID:	000002675
Report Date:	13-AUG-97
Age:	59
Sex:	Female
Setting:	General Medical
Education:	12
Marital Status:	Married

MINNESOTA MULTIPHASIC PERSONALITY INVENTORY-2
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MMPI-2™

THE MINNESOTA REPORT:
ADULT CLINICAL SYSTEM
INTERPRETIVE REPORT

ID: 000002675 REPORT DATE: 13-AUG-97

PROFILE VALIDITY

This is a valid MMPI-2 profile. The client's responses to the MMPI-2 validity items suggest that she cooperated with the evaluation enough to provide useful interpretive information. The resulting clinical profile is an adequate indication of her present personality functioning.

SYMPTOMATIC PATTERNS

The client's MMPI-2 clinical scales are within normal limits, however, she has endorsed some item content that may be important to consider in this evaluation.

She appears to have no sex-role conflicts. Her range of interests includes, but is not limited to, homemaking and cultural activities.

INTERPERSONAL RELATIONS

She has an average interest in being with others and is not socially isolated or withdrawn. She appears to meet and talk with other people with relative ease and is not overly anxious when in social gatherings.

The content of this client's MMPI-2 responses suggests the following additional information concerning her interpersonal relations. She tends to approach social relationships with some caution and skepticism.

DIAGNOSTIC CONSIDERATIONS

This client's MMPI-2 clinical profile is within normal limits and no clinical diagnosis is provided.

NOTE: This MMPI-2 interpretation can serve as a useful source of hypotheses about clients. This report is based on objectively derived scale indexes and scale interpretations that have been developed in diverse groups of patients. The personality descriptions, inferences and recommendations contained herein need to be verified by other sources of clinical information since individual clients may not fully match the prototype. The information in this report should most appropriately be used by a trained, qualified test interpreter. The information contained in this report should be considered confidential.

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